BRINGING COMMON SENSE TO HEALTH CARE REGULATION: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON REGULATORY REFORM

"…When we flood doctors and hospitals with excessive paperwork, patients suffer the consequences…"

—Secretary Tommy G. Thompson at the January 2002 Meeting of the Committee —

PROLOGUE

Dear Secretary Thompson,

In the eight months since we first met in Washington and you asked this Committee to find immediate and effective solutions to the most vexing regulatory problems, we have worked diligently to achieve that goal. We have worked steadily, in subcommittees and the larger Committee, using conference calls and public meetings to accomplish a considerable body of work. We took your challenge to heart and set forth on a mission:

> *To improve the quality of and access to health care and human services for patients and consumers by (1) removing regulatory obstacles to smoothly functioning relationships in the health care system, and (2) promoting appropriate regulatory approaches so that time and resources can be redirected towards patient care.*

In the course of our work we have conducted a series of regional hearings around the country. We brought together panels of doctors, nurses, administrators, beneficiaries, caregivers, and other private citizens. They told us how Federal health programs and drugs and devices regulated by the Food and Drug Administration (FDA) were working for them, and gave the Committee suggestions for improvements in processes or regulations based on their experiences. At every one of the Committee's hearings, we were privileged to listen to comments from the public. The Committee incorporated into its recommendations many ideas from this testimony, in addition to public comments submitted electronically and in writing.

We have seen how the current complexity of law and regulations creates problems for beneficiaries and other consumers, health plans, medical directors, providers, and regulated industries. In some situations, that complexity actually led some medical directors to decisions that kept beneficiaries from receiving needed services. We also discovered that beneficiaries, their families, and other private citizens alike find it exceedingly difficult to obtain information about Medicare, Medicaid, and FDA-regulated products.

In the process of our work, we often discovered that issues identified throughout the hearings are complicated and would require more than a regulatory solution. In some cases, a solution to a problem that is vexing to beneficiaries and providers alike would require legislative solutions, or either significant structural changes or fiscal resources that would require careful decisions by the Administration and the Congress. A dedicated staff has helped us to identify those issues, in spite of challenging time frames. We did not consider the budgetary impact of our recommendations. It may be that when a careful budgetary analysis is complete it could have an effect on a recommendation's feasibility. We are grateful that you began the work of implementing some of these recommendations in the course of our deliberations or after they were adopted, but well before the publication of this final report.

Today, we are sending to you this report that contains our 255 recommendations. While they are crafted to provide specific solutions, we defer to you how best to delegate responsibility for implementing these changes. We hope that you and your colleagues will find the results of this work helpful in improving the functioning of Medicare, Medicaid and the FDA to better meet the health care needs of all Americans.

On behalf of the members of the Committee, it has been a privilege to work in your service.

Douglas L. Wood, M.D.
Chairman, Secretary's Advisory Committee on Regulatory Reform

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ACKNOWLEDGMENTS

Many people helped prepare this report. Their support was critical as the Committee conducted its hearings, analyzed issues, and worked towards consensus on its recommendations.

The Secretary's Advisory Committee on Regulatory Reform is very grateful for the direction and significant support provided to the Committee by the Department of Health and Human Services (HHS) Secretary Tommy G. Thompson, the HHS Regulatory Reform Steering Committee members, and the core Department Staff from the Office of the Secretary, the Centers for Medicare & Medicaid Services, and the Food and Drug Administration dedicated for this effort. Their expert policy direction and strategic advice - as well as their policy analysis, planning, and management and communication skills - were exemplary, thoroughly professional, and essential to helping the Committee accomplish its mission.

Very special thanks also go to those staff at the Department's Headquarters, regional and field offices, contractors, and others who: participated in brainstorming sessions that contributed significantly to the direction and course of the regulatory reform initiative; provided expert testimony as panelists during each public meeting, including the five regional hearing; provided extensive, topic-specific, oral briefings to orient the subcommittees as they moved forward in their deliberations; provided technical assistance on a wide variety of the Department's most vexing and challenging regulatory reform issues; provided extensive outreach to local, regional, and national stakeholders; coordinated the arrangements for Committee meetings and hearings, including scheduling national, regional, State, and local speakers and site visits; and provided substantive analytic support throughout the year on a variety of general and specific issues that ultimately led to the Committee being able to complete its mission. Their unflagging willingness to respond thoroughly and within extremely short time frames, was most appreciated by, and proved to be invaluable to, the Committee members.

The Committee is also grateful to the large number of citizens who graciously took the time to share their thoughts and concerns with the Committee, either in person or via e-mail or letter. Their comments put a human face on the complexity and burdens the health care system is facing today and guided the Committee in its deliberations.

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TABLE OF CONTENTS

FINAL REPORT

EXECUTIVE SUMMARY

There is general agreement that the United States health care system has the potential to provide quality care for all patients. However, there is also general agreement that the current system disrupts the basic relationship between patients and caregivers, frustrates and intimidates many patients with its complexity, and expends health care resources inefficiently. In many cases these disruptions may have an adverse affect on the health of individuals and the health of their communities. The Secretary's Advisory Committee on Regulatory Reform ("Committee") was assembled with the premise that patients would receive better, higher quality care if the health care system was streamlined, and unnecessary barriers were removed.

The Committee recognizes that regulations are necessary to assure basic protections for beneficiaries and other consumers, prevent fraud, maintain and promote access to care, and provide governing direction for large public programs, such as Medicare & Medicaid. It realizes that many concerns about regulations might be alleviated if the regulations achieved their desired goals efficiently. Much of the Committee's work focused on improvements that would attain the efficiency so needed.[1]

The Committee sought to identify solutions to problems that could be immediately implemented. In the evaluation of problems identified by the public, the Committee learned that some problems were not merely regulatory in origin. Rather, solutions to some problems require significant infrastructure changes, significant spending or even legislative changes. During its tenure, the Committee drafted and adopted 255 recommendations, most of which can be implemented administratively.

Currently, accessing care is often difficult because of the hurdles that must be cleared by both patients and providers before care is delivered or pharmaceutical products and medical devices can be made available. The Committee heard testimony and received public comments that many of these hurdles are created by – or result from – regulation. If these barriers interfere with a person's access to needed care or innovative treatments, the system must respond. The Committee recommends that certain requirements be revamped in order to achieve this end.

Through public testimony and written comments, the Committee learned that beneficiaries often spend more time making sense out of paperwork than seeing their health care providers. The Committee sought opportunities to reduce paperwork and improve the quality of care provided to beneficiaries.

The development of complex regulations often has the unintended consequence of creating confusion about the intent behind the regulations and how the regulations should be implemented. Problems are inevitable when people are asked to comply with rules they do not understand. Many problems brought before the Committee are linked to the issuance of complex regulations which then require additional clarifying documents and guidance. Too often, those affected by the regulation (beneficiaries, physicians and other providers, and health plans) do not know where to get needed information. Some information available from contractors (who are

[1] In many instances in this report, the Committee employs the term "regulations" to generally describe governmental rules, requirements, guidelines, and other directive or informational communications.

the face of Medicare for beneficiaries and providers) is not always easy to understand. Committee recommendations in this area urge the Department to speak more clearly, listen more closely, and respond more fully in its communications with beneficiaries and providers.

Regulatory requirements, mechanically enforced, can stifle innovation in service delivery and quality improvement. Health care regulation must adapt to market changes and evolving relationships within the healthcare system. The Committee heard testimony recommending that the Department discard a "one-size-fits-all" approach when implementing regulations. The recommendations that the Committee developed reflect the view that flexible implementation of regulations can strengthen the programs under the Department's purview. Moreover, once a rule or regulation is in place, its effectiveness in achieving its intended purpose should be periodically evaluated.

The health care delivery system has changed dramatically since enactment of the Food, Drug and Cosmetic Act in 1938, and the creation of Medicare & Medicaid in 1965. Advances in medicine and technology allow seniors and persons with chronic diseases and disabilities to live longer, healthier lives. While health care has progressed rapidly, in many instances the rules and regulations that govern Federal health care programs have not. As a result, patients, providers, and regulated industries feel encumbered by outdated rules or frustrated by their inability to take advantage of current technology. The result is often a serious delay in accessing needed health care services.

The Committee's recommendations address many areas of concern, and devote considerable attention to those areas identified in public comment as problematic. Each chapter of the report highlights Committee recommendations to illustrate key themes. The full list of Committee recommendations can be found in Appendix B. In much of the process used by the Committee to conduct its work, the Committee asked HHS staff to provide careful technical review by developing assessments of the ease of implementing a proposed solution. For example, the Committee did not consider the budgetary impact of its recommendations. It may be that when a careful analysis is complete it could have an effect on a recommendations' feasibility. In addition, the Committee recognizes that there are also statutory or, structural limitations that must be considered before HHS makes final decisions about which of the Committee's recommendations can be quickly implemented.

The Committee's unfinished business is summarized in Appendix C. The reader is cautioned that the presence of an item in this Appendix does NOT imply endorsement nor does it imply rejection. The full text transcript for all SACRR meetings, including the final meeting on November 21, 2002, is available at http://www.regreform.hhs.gov.

CHAPTER 1

THE IMPACT OF REGULATION ON ACCESS TO CARE

" We recognize the need to enhance the trust of Americans that they will be well cared for, served, and protected…" – Mission Statement, Secretary's Advisory Committee on Regulatory Reform.

The members began with the premise, that while regulations are necessary to implement government programs, complex and burdensome regulations create unnecessary barriers and restrict access to services by disrupting the relationship between patients and their caregivers. By devoting resources to navigating complex rules and regulations, healthcare providers have less time to focus on delivering high quality care.

Medicare is the largest Federal health program, providing coverage for 40.7 million American seniors, individuals with end-stage renal disease (ESRD), and individuals with other disabilities. It is projected to expend approximately $254.8 billion in fiscal year 2003. The Medicaid program provides coverage to 40.4 million Americans, and is projected to expend $158.7 billion in fiscal year 2003. There are 6.2 million Americans who are eligible for both Medicare & Medicaid. Today there are approximately 885,500 doctors, 6,000 hospitals, 155 Medicare+Choice plans, 14,800 skilled nursing facilities (SNFs), 17,000 nursing facilities (NFs), 7,100 home health agencies (HHAs), and other providers participating in one or both of these programs. A wide range of Federal, State and local regulations govern these providers, suppliers, health plans, and practitioners who deliver care and other services. Even beneficiaries must comply with certain rules. These regulations change at varied times, often have a direct impact on access to care, and often result in unintended consequences.

While most of the Department of Health and Human Services' (HHS's) regulations are intended to provide the operational and policy details for participation in public programs such as Medicare & Medicaid, they reach far beyond the individual programs, affecting other patients and providers as well. For example, regulations that list requirements for hospitals to participate in Medicare, referred to as the "Conditions of Participation" or "COPs," serve to establish minimum standards for quality that provide protections for all patients.

There is general agreement that the United States health care system has the potential to provide high quality care for all patients. Currently, however, accessing that care is often difficult because there are hurdles that must be cleared, by both patients and providers, before care is delivered. Many of these hurdles are created by – or are a result of – regulation. Government regulations directly and indirectly affect where patients receive their care, how providers deliver the care, and the amount paid for care. Many beneficiaries navigate the system with little direct disruption; for others the "cost" of regulation is greater uncertainty and disruptions in care. When these regulatory barriers interfere with a person's access to needed care, the system must respond. This chapter addresses those impediments to the patient's goal of obtaining high quality care and the provider's goal of delivering that care.

EMERGENCY CARE AND EMTALA

The Committee examined carefully the regulations for implementing the Emergency Medical Treatment and Active Labor Act (EMTALA) of 1986. Congress passed EMTALA in response to reports that hospitals were refusing to treat some patients based on their ability to pay and that several deaths occurred subsequent to such refusal. EMTALA was designed to prevent a hospital from refusing to screen and provide appropriate emergency treatment to patients seeking care in the Emergency Department. The law requires hospitals to conduct a medical screening examination for any patient who comes to an Emergency Department. EMTALA was intended to ensure that all patients have access to emergency care, regardless of their ability to pay. But what was designed as a straightforward guarantee of care in emergency cases has yielded a myriad of confusing regulations that, in some cases, have reduced access to care.

The Committee heard testimony from physicians, hospital administrators, and ambulance drivers, expressing their difficulty interpreting the complex and confusing EMTALA regulations. Coupled with severe monetary penalties, private lawsuits, and the threat of termination from all Federal programs for violating EMTALA, physicians and hospitals noted that current regulations create an impediment to care. In particular, the law takes force when a patient "comes to the hospital," but the definition of hospital boundary lines is overly broad and may prevent some ancillary facilities from taking the most appropriate action (e.g., calling 911) in an emergency situation. In addition, the EMTALA regulations prevent hospitals from talking to patients about their insurance status prior to screening. This may conflict with other Medicare rules that require advance beneficiary notices (ABNs) to be provided before billing a patient for services not covered under Medicare. Unable to follow both EMTALA and Medicare rules, hospitals may, at one time or another, forego Medicare payments rather than risk enormous penalties.

The Committee heard that hospital medical staff and legal counsel are uncertain when their EMTALA obligations end. Consequently, some doctors (particularly surgical specialists) are unwilling to take on-call duty, concerned about the risk of being uncompensated and responsible for open-ended follow-up care. Specialists are particularly concerned about the on-call time that they are required to spend at the hospitals where they have admitting privileges.

Finally, hospital administrators described the Centers for Medicare & Medicaid Services (CMS) review procedures for alleged EMTALA violations that are inconsistent from one regional office to another and often focus on minor technical errors or incomplete paperwork, rather than the entire episode of care. Current procedures require the forwarding of alleged EMTALA violations involving medical judgment or physician action for peer review by Quality Improvement Organizations (QIOs), only after initial State Agency review, which may take up to 15 days. Delay in getting clinical case review by QIOs is believed to contribute to provider frustration.

In response to a thorough discussion of the effect of EMTALA regulations on access to care, the Committee makes the following recommendations:

> ***Recommendation:*** **Modify the definition of "hospital property" to be only the Emergency Department and any other health facility that holds itself out to the public as being available to provide emergency or urgent care, as well as the "immediate vicinity" to the hospital property (such as the hospital lawn,**

parking lot, waiting room, or similar location) in situations where someone seeking emergency care is physically unable to proceed to the actual Emergency Department or urgent care facility.

Recommendation: **Issue immediate interpretive guidance that use of community-based Emergency Medical Service (EMS) protocols, including established 911 protocols, is not a violation of (EMTALA).**

Recommendation: **Review, update, and clarify in regulation and interpretive guidance what is mandated by EMTALA for the physician; clearly distinguish physician medical staff responsibilities from hospital responsibilities. In particular, CMS guidance should provide an explanation of whether there is a recommended threshold for the application of EMTALA as it relates to the number of specialists and type of specialists on staff who are available to be "on-call" at a particular hospital (e.g., identify safe harbors when physician specialists who are in short supply are "on-call" at more than one hospital at the same time.)**

Recommendation: **Define limits of EMTALA by clarifying that EMTALA requirements end when qualified medical staff have made a decision: (a) that no emergency exists; (b) that an emergency exists and the patient is stabilized; (c) that an emergency exists which requires transfer to another facility where the EMTALA obligation rests with the transferring hospital until arrival at the receiving hospital; or (d) that an emergency exists and an unstable patient (who) is admitted to the hospital has been stabilized.**

Recommendation: **Mandate review by QIOs early in the process and improve training of regional offices and State agencies to improve performance and consistency of review of EMTALA complaints. (The CMS Atlanta Regional Office procedures should be used as a model.)**

RURAL HEALTH CARE

Regulatory impediments to providing quality health care exist in a variety of settings. Rural providers are geographically isolated and serve a smaller population base that has a disproportionately older population with lower household incomes. Given these factors, rural providers face unique challenges that make them particularly vulnerable to operating pressures created by regulations. In addition, rural providers often experience difficulty in attracting other health care professionals to practice in their location. Rural hospitals and clinics often rely on temporary (*locum tenens*) doctors, and it can take months to get them registered with Medicare contractors, which delays billing and creates severe cash flow problems. Commenters asserted that the process to register doctors should be faster and more uniform, preferably electronic.

Rural providers also encounter severe financial pressures related to dependence upon government funding sources. The Committee heard from members of the rural health care community that new Federal initiatives are particularly difficult to implement because they require investment in new computer equipment and training, and the providers lack access to the necessary capital.

Recognizing that rural providers need special assistance in order to assure access to services for seniors, individuals with disabilities, and other patients, Congress created a number of special programs and payment categories. In a report to the Committee, the HHS Office of Rural Health Policy stated that there are over 200 discrete HHS programs that affect rural communities, each with slightly different requirements and designed to address different problems. Each program or payment system, for example, defines the term "rural" slightly differently: by population, by geographic location, by health care provider shortage, and/or by transportation difficulties. In addition each program or payment system has its own unique set of regulations.

Health care providers in rural America, short on time and without administrative staff to research funding opportunities, find it difficult to identify and prepare the necessary paperwork to participate in these special programs. In addition, patients in rural areas may not have access to support services to assist them in completing eligibility forms. Thus, beneficiaries may not receive assistance from the very programs designed to help them.

Rural practitioners recommended that HHS conduct more research on rural health needs and give rural providers one clear and consistent office to work with for all of their waiver requests, grant applications, and technical assistance. Testimony presented to the Committee clearly articulated the belief that regulations implementing the many programs and payment systems designed specifically for rural health care providers are prepared without adequate input from the providers who will be governed by the regulations. This is of great concern to the Committee. The rural health care system must not fail; in many areas, the hospital or other entity is the provider of first and last resort.

In response to the testimony and the Committee discussions, the recognition of the important services rural providers deliver, and the need for those services to continue, the Committee recommends:

> ***Recommendation:*** **Consolidate existing definitions of rural into one communicable definition. [Currently "rural" has a different meaning for hospitals versus health clinics.]**
>
> ***Recommendation:*** **Intensify outreach efforts to educate rural health providers about the specific programs that focus on rural communities and invest in rural "best practices." Maximize the ability of HHS websites to connect rural health providers to information about all appropriate resources, technical and financial assistance programs, and best practice models for rural communities.**
>
> ***Recommendation:*** **Develop a legislative proposal with Congress to address the current fragmented approach to rural Medicare payment policy (e.g., Sole Community Hospitals, Critical Access Hospitals, bonus payments for rural primary care physicians, etc.) with an eye towards replacing this fragmented approach with a system that recognizes the unique operating characteristics of rural providers in all settings.**

One of the most serious problems facing rural communities and their health care system is a shortage of qualified health care professionals. Although there are shortages of various health professionals in many parts of the country, the impact in the rural area can be especially severe. Health care decision makers should take steps to address this shortage. The Committee also recognizes that some proposed actions are statutory and beyond the scope of its charter, for example, that the payment system for small rural hospitals be changed and that Certified Registered Nurse Anesthetists (CRNAs) be recognized as providers of service. The Committee believes that implementing the following recommendations would help ameliorate the shortage of rural health professionals.

Recommendation: **Address rural workforce issues:**

- **Consider continuance of "hold harmless" provisions under the prospective payment system for ambulatory services.**
- **Recognize Advanced Registered Nurse Practitioners as providers of services.**
- **Retain the State's statutory flexibility regarding use of CRNAs.**
- **Recognize the need for educational support for preparation of rural healthcare providers.**
- **Recognize the impact of tighter immigration regulations on access to foreign physicians and immigrant entry-level caregivers and the need to work with rural healthcare providers to resolve these issues.**

Recommendation: **Urge the National Advisory Committee on Rural Health to advise HHS on a process whereby HHS works with knowledgeable representatives of rural America to analyze the impact of a new statute or regulation on the rural delivery system before it is enacted.**

A BENEFICIARY-CENTERED SYSTEM

Nearly 20 years ago, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research wrote that a person should be able to access health care services without "excessive burdens." Patients trying to obtain needed health services should not be encumbered by the need to read the fine print on an insurance card, when using clear language and publishing in legible font is possible.

Access to care and the regulatory hurdles that providers must overcome in order for their patients to receive care are of deep concern to the Committee. While most Medicare rules and regulations are administered consistently across the country, coverage of some services varies at the local level. Because of this variation, providers are often unable to determine with certainty if some services will be covered. In such cases, the statute requires providers to issue an ABN to the patient in order to later bill the patient for the care that Medicare does not cover. While intended to give beneficiaries a warning, the ABN, and the inability to determine if a service will be covered before it is delivered, imposes a constraint on the delivery of care. Some of the problems could be relieved by a system to furnish prior coverage determinations to both beneficiaries and providers. Recognizing the significant resources required to implement such a system for millions of beneficiaries, the Committee urges the Secretary to consider such changes.

ACCESS TO SAFE MEDICAL PRODUCTS AND RELATED INFORMATION

Access to health care services includes access to safe medical products. The Food and Drug Administration (FDA) regulates such products to determine if they are safe and effective. While all products carry some risk, the FDA determines that, if products meet certain standards, they can be made available to the public. Before a medical product can be marketed, it must undergo extensive testing of its safety and efficacy. The FDA Modernization Act of 1997 (FDAMA) provided for the development of a clinical trials database for drugs and biologics. The database is maintained by HHS and is the place where firms can advise consumers of clinical trials that they are conducting. Participation by firms in the clinical trial database is mandatory for drugs used to treat serious and life threatening conditions and for efficacy trials, and it is voluntary for other type of products or trials. Some clinical trials have trouble attracting human research subjects, so making the database available to the public could help make people better aware of the trials that are available. Since the primary users are consumers, their input about the types of information that would be helpful to include in the database will be critical to success. The Committee believes this resource should be expanded to increase access to new treatment opportunities.

> ***Recommendation:*** **Add information on clinical trials for (medical) devices (with investigational device exemption designations) to the clinical trial database for drugs and biologics. Seek stakeholder input in this process, while ensuring confidentiality of proprietary information. Establish, as a priority, the implementation of this database for all FDA-regulated products**.

Once on the market, FDA-approved products must be used appropriately and safely. The Committee learned that, with accurate, timely, and consistent information about the appropriate and safe use of medical products, providers and consumers can minimize risks. The FDA could eliminate errors caused by confusing brand names by ensuring that products are carefully named. The Committee believes that the labeling of medical products should be clear, with standardized presentation and definitions. The Committee also believes that using bar coding technology could reduce medical errors that occur in hospitals, and therefore, it recommends that the FDA implement packaging requirements to facilitate development of such a system by hospitals. Consumers and providers could learn how to use medical products safely and avoid potentially dangerous interactions between and among drugs, foods, and dietary supplements through an interactive database. HHS should take steps to improve current adverse event reporting mechanisms (like MedWatch), or study the development of new information technology reporting systems for adverse events. In response to the testimony and public comments, the Committee makes the following recommendations:

> ***Recommendation:*** **Adopt safe labeling practices for all FDA-regulated products to improve patient safety and decrease avoidable adverse drug events. For example, adopt labeling standards with respect to label format, information placement, information presentation and standardized definitions (and measurements).**

> ***Recommendation:*** **Issue regulations that would require all appropriate FDA-regulated products to be packaged to take full advantage of appropriate**

administration and patient identification technologies to prevent medical errors.

DUAL ELIGIBILITY FOR MEDICARE AND MEDICAID

Medicare beneficiaries who have low incomes will often qualify for additional assistance under their State's Medicaid program. When individuals are "dually" eligible, Medicaid can help pay for Medicare out-of-pocket expenses. For example, for some dually eligible individuals, Medicaid pays their co-payments, deductibles, monthly Medicare Part B premiums, and services not covered by Medicare. Preceding a beneficiary's Medicaid eligibility determination, Medicare Part B monthly premiums are deducted from the Supplemental Security Income (SSI) or Social Security Disability Income (SSDI) payment. Once beneficiaries are determined eligible for Medicaid, those Part B premium payments are refunded within ninety days. If the refund is delayed, the amount of the refund grows. If the delay in determining eligibility is lengthy, the amount of the refund may be significant and may endanger the beneficiary's eligibility for Medicaid by raising assets above Medicaid asset limits. To address this problem, the Committee recommends:

Recommendation: **Institute immediately a policy requiring States to exempt lump sum Medicare Part B premium refunds – currently allowed to be deducted from the Social Security benefit payments of a dually eligible beneficiary during the period in which the beneficiary's *initial* Medicaid eligibility is being determined – from being counted as an asset in determining the beneficiary's continuing eligibility for Medicaid.**

In conclusion, the Committee is focusing on providing consumers and patients with access to safe and efficient products and services. This chapter addresses recommendations that can be implemented administratively as well as those that require Congressional action. This blending simply highlights the complexity of the problems facing the health care system. As each of the subsequent chapters will make clear, reducing that complexity is a difficult, but not impossible task.

Master List of SACRR Committee Recommendations [2]
Chapter 1

No.	Adopted Recommendations	Full Committee Action
17	Modify the definition of "hospital property" to be only the Emergency Department and any other health facility that holds itself out to the public as being available to provide emergency or urgent care, as well as the "immediate vicinity" to the hospital property (such as the hospital lawn, parking lot, waiting room, or similar location) in situations where someone seeking emergency care is physically unable to proceed to the actual Emergency Department or urgent care facility.	Adopted May 2002, with dissent from Mr. Martin.
18	Issue immediate interpretive guidance that use of community based Emergency Medical Service (EMS) protocols, including established 911 protocols, is not a violation of the Emergency Medical Treatment and Active Labor Act (EMTALA).	Adopted May 2002
19 *	Exclude from the purview of EMTALA, patients who are referred to the Emergency Department for diagnostic or scheduled therapeutic services, unless the diagnosis is part of the EMTALA-required screening or the treatment is part of the EMTALA-required stabilization.	Adopted May 2002
20 *	Resolve the Medicare coverage issues underlying the need for advanced beneficiary notices (ABNs) to have to be provided in the Emergency Room. Consider waiving the requirement for ABNs and the associated denial of coverage in emergency room and other urgent care settings.	Adopted May 2002
21	Issue interpretive guidance that EMTALA does not apply: • In the event of an attack involving multiple casualties and where hospitals use an established disaster plan. • In the event of bioterrorism, or the threat of bioterrorism, to those hospitals directly affected and where hospitals follow a community based, regional or Centers for Disease Control (CDC) directed protocol (especially for highly contagious outbreaks like smallpox.)	Adopted May 2002
22	Review, update, and clarify in regulation and interpretive guidance what is mandated by EMTALA for the physician; clearly distinguish physician medical staff responsibilities from hospital responsibilities. In particular, CMS guidance should provide an explanation as to whether there is a recommended threshold for the application of EMTALA as it relates to the number of specialists and type of specialists on staff who are available to be "on-call" at a particular hospital. (e.g., identify safe harbors when physician specialists who are in short supply are "on-call" at more than one hospital at the same time.)	Adopted May 2002
23	Require that hospitals be notified when EMTALA investigations are completed, regardless of the outcome.	Adopted May 2002
24	Make Quality Improvement Organization (QIO) review mandatory early in the process and improve training of regional offices and State Agencies to improve performance and consistency of review of complaints. (The CMS Atlanta Regional Office procedures should be used as a model.)	Adopted May 2002
110 *	Consolidate existing definitions of rural into one communicable definition. [Currently rural can mean one thing for a hospital and another for a rural health clinic.]	Adopted June 2002
111	Disaggregate data describing rural healthcare delivery from data describing urban healthcare delivery to ensure accurate representation of resources and expenses for the purposes of rule making and rate setting.	Adopted June 2002
112	Eliminate the ceiling regarding the maximum number of surgeries a rural hospital can perform in order to bill Part A for Certified Registered Nurse Anesthetist (CRNA) services instead of Part B, to eliminate the burden of having to get Part B provider numbers for rural CRNAs.	Adopted June 2002

[2] An asterisk [*] next to the number of a recommendation indicates that legislative action may be required in order for the Department to implement the Committee's recommendation. See Appendix B.

No.	Adopted Recommendations	Full Committee Action
113 *	Establish a Part A fee schedule for CRNA services. [This schedule could be used to reimburse rural hospitals in lieu of the pass-through cost of CRNA services.]	Adopted June 2002
114	Allow hospitals, skilled nursing facilities and other affected entities to file an annual, renewable three-year geographic reclassification application. Consult with the Office of General Counsel and industry legal experts to determine if the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 does indeed permit the filing of renewable, three-year geographic reclassification applications. Accept the first renewable application by September 1, 2003 if it is determined that three-year renewable geographic reclassification applications are permitted by statute.[3]	Adopted June 2002
115 *	Address rural workforce issues • Consider continuance of "hold harmless" provisions under the Prospective Payment System for ambulatory services • Recognize Advanced Registered Nurse Practitioners as providers of services • Retain the State's statutory flexibility regarding use of CRNAs • Recognize the need for educational support for preparation of rural healthcare providers • Recognize the impact of tighter immigration regulations on access to foreign physicians and immigrant entry-level caregivers and the need to work with rural healthcare providers to resolve these issues.	Adopted June 2002
116	Develop a pilot certification survey process for Critical Access Hospitals (CAHs) that would entail a single survey to examine all aspects of the hospital's operations and allied health services.	Adopted June 2002
117 *	Develop a legislative proposal with Congress for a single certification survey process for all providers of rural health services, including hospitals, skilled nursing facilities, home health agencies, rural health clinics, community health centers, etc., based on the results of the single survey process for CAHs.	Adopted June 2002
118	Urge the National Advisory Committee on Rural Health to advise HHS on a process whereby HHS works with knowledgeable representatives of rural America to analyze the impact of a new statute or regulation on the rural delivery system before it is enacted.	Adopted June 2002
119 *	Develop a legislative proposal with Congress to address the current fragmented approach to rural Medicare payment policy (e.g., Sole Community Hospitals, CAHs, bonus payments for rural primary care physicians, etc.) with an eye towards replacing this fragmented approach with a system that recognizes the unique operating characteristics of rural providers in all settings.	Adopted June 2002
126	Clarify the policy that in the event that a Medicare + Choice Organization (M+CO) becomes insolvent, and can no longer pay the provider network, the beneficiary is still responsible for any pre-determined obligations (e.g., co-pays, etc.) but should not be balance-billed for any unpaid services beyond that obligation.	Adopted June 2002
131	Define limits of EMTALA by clarifying that EMTALA requirements end when a qualified medical person has made a decision: • that no emergency exists**;** • that an emergency exists and the patient is stabilized**;** • that an emergency exists which requires transfer to another facility where the EMTALA obligation rests with the transferring hospital until arrival at the receiving hospital; or • that an emergency exists and an unstable patient (who) is admitted to the hospital has been stabilized.	Adopted June 2002

[3] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendations	Full Committee Action
132	Create an Emergency Services Cooperative Project that would follow the format of the Diabetes and Cardiovascular Quality Improvement Project. This should be developed and implemented with a scientific and technical advisory board of emergency physicians, hospitals, first responders, emergency transportation specialists, consumers and other advisers. This group should also guide development of future regulations that would assure availability of effective emergency services in all parts of the country. This group would include on-call physicians (medical and surgical specialists who provide care for emergencies) as part of the scientific and technical advisory board for the Emergency Services Cooperative Project. In the future this group should take on thorny issues such as reimbursement mechanisms for EMTALA related-services when patients don't have insurance; foster appropriate consultation with and involvement by QIOs; appropriate due process for hospitals and health care professionals before CMS can issue a public notice of termination and proceed with a termination letter.	Adopted June 2002
133	Clarify the "prudent layperson" concept as per the EMTALA NPRM as follows: • The term "prudent" has a commonly understood meaning, and we would refer the reader to the general dictionary definition to this term. • A "layperson" refers to an individual with an average knowledge of health and medicine, as the definition of "emergency medical condition" states.	Adopted June 2002
159	Intensify outreach efforts to educate rural health clinics and providers about the specific programs that focus on rural communities and invest in rural "best practices." Develop a rural health care section on relevant HHS websites for providers that will include all appropriate resources, technical and financial assistance programs, and best practice models for rural communities.	Adopted June 2002
164	Exclude from Medicare local medical review policies (LMRPs) those diagnostic services ordered by a qualified medical professional when medically necessary pursuant to satisfying the hospital's EMTALA obligations; and require fiscal intermediaries (FIs) and carriers to pay for diagnostic services when ordered and provided in connection with satisfying the hospital's EMTALA obligation.	Adopted June 2002
192	Convene by September 1st, 2002 with recommendations by July 1st, 2003 and a pilot ready to implement by September 1st, 2003, an inter-agency working group consisting of CMS, State Medicaid Directors, and the Social Security Administration (SSA) to work on an improved system for timely and accurate identification, enrollment, and notification of dual eligibles.[4]	Adopted June 2002
193*	Identify the "best practices" of States which have been most successful in identifying and enrolling dual eligible beneficiaries (QMBs, SLMBs, QI-1s, QI-2s), including through electronic data matches, and encourage through incentives, use of those best practices in other States that are not as successful. Develop pilot studies and other demonstrations of innovative methods to integrate Medicare & Medicaid data on a near real time basis, so that States could be provided continuous ability to access and analyze their dual eligibility data on a command basis.	Adopted June 2002
194	Institute in those 15 States where there is no electronic information exchange to identify dual eligibles, data match agreements between the State, and CMS and/or SSA. Until those data match agreements have been operationalized, develop or refine interim working agreements between States and CMS and/or SSA to ensure timely notification about dual eligibility and enrollment. Work to continuously improve the quality and accuracy of the Medicaid eligibility data States bring to CMS and/or SSA, for new and existing electronic information exchanges to identify and enroll dual eligibles.	Adopted June 2002

[4] One of these dates has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendations	Full Committee Action
195	Determine what barriers exist to State Medicaid Agencies complying with Federal timelines for enrolling qualified Medicare beneficiaries into premium assistance programs, and seek remedies (e.g., best practices for technical problems, information technology improvements, etc.) to remove those barriers. (The timelines apply only after an individual has filed an application through the State Medicaid Agency.)	Adopted June 2002
196	Institute immediately a policy requiring States to exempt lump sum Medicare Part B premium refunds, currently allowed to be deducted from the Social Security benefit payments of a dually eligible beneficiary during the period in which the beneficiary's *initial* Medicaid eligibility is being determined, from being counted as an asset in determining the beneficiary's continuing eligibility for Medicaid.	Adopted June 2002
197 *	Look at States that have enacted a single enrollment form for all eligible programs such as the District of Columbia. Develop a simplified, model, "one-stop-shop" application form that constitutes a formal beneficiary enrollment into all eligible Federal/State entitlement or assistance programs (for example: Medicaid, food stamps, Women, Infants and Children (WIC), Housing, etc.). To the maximum extent possible, work with relevant agencies to standardize the form in order to develop an electronic enrollment process. Immediately have HHS look at those State programs that are most successful in enrolling dual eligible beneficiaries into all eligible Federal/State entitlement or assistance programs (especially those programs under the auspices of the Secretary of HHS.)	Adopted June 2002
198	Determine if States provide assistance to individuals who require assistance to complete beneficiary enrollment applications for Federal/State entitlement or assistance programs, consistent with applicable Federal, State and local laws, requirements, and established policies, including but not limited to, those regarding individuals with Limited English Proficiency (LEP) and the Americans with Disabilities Act. Work with States to eliminate any technical barriers they may encounter to meeting those requirements and share best practices that demonstrate effective methods of doing so.	Adopted June 2002
219	Develop a database for practitioners, patients and caregivers to help prevent known potential adverse interactions between and among drugs, foods and dietary supplements. Once a patient, caregiver, or any medical professional enters a patient's complete drug regimen into this database, the program would alert the patient to the level of risk and/or benefit of any known potential interactions. (For this recommendation, the term "drug" includes prescription and over-the-counter medications, and the term "dietary supplements" include but are not exclusive to herbal and nutritional supplements. An existing example can be found on the web at www.aidsmeds.com.)	Adopted June 2002; Re-Adopted September 2002
220	Publicize the user-friendly, drug-food-dietary supplement interactions database to mitigate any increases in health care costs due to adverse events. (For this recommendation, the term "drug" includes prescription and over-the-counter medications, and the term "dietary supplements" include but are not exclusive to herbal and nutritional supplements.)	Adopted June 2002; Re-Adopted September 2002
221	Immediately launch an educational and information campaign to educate patients and all healthcare professionals about the MedWatch system (an adverse event reporting system operated by the FDA) to increase the reporting of adverse events until an improved, automatic information technology system is established.	Adopted June 2002
223	Use the Centers for Education and Research on Therapeutics (CERTs) for collection of adverse event information from all healthcare providers, both public and private. Use CERTs to develop a central repository of drug adverse event reports from all healthcare providers. CERTs should conduct Phase IV Trials when, in consultation with the FDA, it has been decided that a Phase IV Trial may be necessary to answer new questions that arise from newly reported adverse events.	Adopted June 2002
234	Promote the broadest dissemination of the "Best Pharmaceuticals for Children Act" mandate for a 1-800-Toll-Free number for reporting of adverse drug events when promulgating a final rule under P.L. 107-109. The toll-free number should appear in an easily identifiable location. The Committee also recommends that manufacturers voluntarily begin placing this number on unit of use or ready-to-dispense prescription packages to minimize the impact on pharmacy.	Adopted September 2002

No.	Adopted Recommendations	Full Committee Action
235	Adopt safe labeling practices for all FDA-regulated products to improve patient safety and decrease avoidable adverse drug events. For example, adopt labeling standards with respect to label format, information placement, information presentation and standardized definitions (and measurements).	Adopted September 2002
238*	Shift from doing name safety testing, in most cases, to reviewing data from sponsors who follow protocols designed to evaluate the potential for look-alike and sound-alike errors with generic and proprietary names prior to approval of FDA-regulated drugs. Use information gathered from the name safety research to improve patient safety by minimizing post-marketing medication errors linked to name similarity and practitioner confusion.	Adopted September 2002
239	Encourage all relevant parties (FDA, other HHS agencies, consumer groups, industry, pharmacy groups) to issue educational materials on the reporting of adverse events targeted to the patient and health care provider audiences. Such materials should be designed to encourage reporting of appropriate adverse events by patients and health care providers.	Adopted September 2002
240*	Issue regulations that would require all appropriate FDA-regulated products to be packaged to take full advantage of appropriate administration and patient identification technologies, and consequently, to prevent medical errors.	Adopted September 2002
246*	Add information on clinical trials for devices (IDEs) to the clinical trial database for drugs and biologics. Seek stakeholder input in this process, while ensuring confidentiality of proprietary information. Establish, as a priority, the implementation of this database for all FDA-regulated products.	Adopted September 2002
247	Develop separate MedWatch forms for pharmaceutical products and medical devices.	Adopted September 2002

CHAPTER 2

REDUCING PAPERWORK BURDEN

> *"My doctor constantly reminds me that he's sick and tired of the paperwork…It's not much fun to go to a doctor who's not happy." – Lena Archuleta, Medicare Beneficiary and Panelist at Denver Hearing, reporting the comments of a neighbor.*

The Department of Health and Human Services (HHS) needs to reduce beneficiary and provider paperwork where it is practical and feasible to do so, particularly for the Medicare program. In considering its recommendations, the Committee recognizes that reducing paperwork would allow more time for direct patient care, permitting improved health care quality and improved patient safety. Throughout the Committee's deliberations, it became clear that data collection efforts have tended to evolve from the circumstances at the time they were implemented, resulting in a patchwork of disparate data instruments and processes. This purpose and context had to be considered before recommending a requirement's elimination. Consequently, the Committee deliberated the merits of every proposal, and recommends only those changes that do not detract from HHS efforts to improve quality or refine payment accuracy. Public testimony at regional hearings and written comments were very informative and demonstrate that beneficiaries spend considerable time filling out duplicative paperwork or answering the same questions repeatedly. Nurses, whose time is in great demand, in part, due to the current shortage of nurses, testified that they spend more time completing paperwork than providing care. The Committee makes nearly 32 recommendations on ways HHS can reduce paperwork. Its priorities are discussed in detail in this chapter.

Documentation and related activities connect a wide variety of patients, providers, and payers in the health care delivery system. Forms and other required documents often identify the patient's diagnosis, the services provided, the procedures performed, and by whom care was delivered, and are used to estimate providers' costs for furnishing services and claim payment. Both the number and complexity of government forms have proliferated as the Medicare program has evolved from its original 1965 design.

The Centers for Medicare & Medicaid Services (CMS) uses data collected from these forms to refine and update payment systems. CMS also requires providers to submit some information beyond what is needed for making accurate payments. The information that the Department collects is often an important resource, offering data regarding both medical care practice and outcomes. Some of the additional data are used for program integrity, and other functions such as assessing and improving quality, and research. The Medicare program may require additional documentation to determine if services meet certain medically necessary standards, and to determine if another payer should pay for the services. There is also information that is duplicative or extraneous, and is not needed for patient care, payment, or quality management. The collection, transmission, and storage of this unneeded information creates work that does not directly help anyone in the health care system.

As the Committee considered this issue and other data reporting requirements, a key theme emerged from the deliberations and public comments: if data are collected, they should be used

for the stated and authorized purpose, be it paying providers appropriately, improving quality of care, or improving plans of care. HHS should eliminate data collection requirements that have no direct use. Routine collection of data for purely academic reasons or undefined future use unreasonably burdens the health care system. This chapter focuses on a few key areas.

OUTCOME AND ASSESSMENT INFORMATION SET (OASIS)

Medicare requires the use of a standardized questionnaire – the Outcome and Assessment Information Set (OASIS) – by home health agencies to assess patients' physical, mental, and social conditions. OASIS was developed 15 years ago for providers to integrate continuous quality improvement into home care. The Omnibus Budget Reconciliation Act of 1987 (OBRA '87) requires home health agencies (HHAs) to evaluate patients and establish plans of care, and mandates that Medicare monitor the quality of home care and services with a standardized, reproducible assessment instrument to attain and maintain the highest practicable functional capacity of each individual patient. OASIS started with approximately 300 elements and evolved into 79 core elements.

The Balanced Budget Act of 1997 required CMS to develop and implement a prospective payment system for home health. CMS (then, the Health Care Financing Administration) selected OASIS as the base reporting tool, which now has multiple uses, including payment, quality, and care planning. It is administered at designated intervals, and at other major points in a patient's care cycle – e.g., when a patient begins home care, transfers to a hospital, returns from the hospital, or is discharged from home care. While the Committee received testimony that OASIS and other instruments generate valuable information and provide a thorough patient assessment, the Committee also heard significant concerns about, and some constructive criticism of, OASIS.

Testimony noted that the forms were too long, had too many questions, were required too frequently, and consumed too much HHA staff time. In particular, HHA staff noted that they found it difficult to complete the assessment and enter the data electronically in the allotted timeframes. One representative of an HHA testified that her agency's nurses require one and a half to two hours to complete the OASIS assessment, time that is not available to provide direct patient care. The provider also noted that, on average, it takes a nurse six months to learn how to administer this assessment proficiently. In addition, once the information is collected, it then requires, on average, 17 minutes for an experienced data entry person to input the assessment data into the system. The Committee heard that it is difficult for HHAs to submit accurate assessments within the time frame required and that once they enter data, there are often additional delays before the data are accepted as final. Several witnesses suggested that excessive paperwork was a negative factor in retaining nurses. Finally, the Committee heard suggestions that CMS should streamline the assessment tool itself.

In light of the testimony and public comments to reduce excessive paperwork, the Committee developed recommendations that would preserve the useful and necessary aspects of the OASIS tool, while allowing nursing personnel in HHAs to spend more time providing care. These recommendations are listed below:

Recommendation: **Change OASIS policies to better reflect actual HHA operations:**

- **expand the time for completion of the OASIS instrument, for example, from 5 days to 7 days;**
- **change the lock-in time for the OASIS instrument, for example, from 7 days to 14 days. (HHA nurses, especially in rural areas, come to the HHA central office only once a week.)**

Recommendation: **Ensure that data collection efforts facilitate development of care plans.**

- **Delete elements that are duplicative or not used for payment (including risk adjustment), quality management, or survey purposes. CMS should particularly scrutinize elements listed in Miami testimony including MO190, MO340, MO640-680, and MO780.**
- **Eliminate OASIS encounters that are not used for payment, quality management, or survey purposes.**

Recommendation: **Adopt a continuous quality improvement process to keep the OASIS tool current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide OASIS use (measure work-ups, interpretation of data quality, interpretation of results, quality reporting, assessment of need for new measures.)**

Recommendation: **Clarify the definition of "significant change." Consider using re-hospitalization as a proxy for "significant change."**

MINIMUM DATA SET (MDS)

The Committee examined the regulatory issues related to the Minimum Data Set (MDS), which specifies patient assessment data that Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities (NFs) are required to collect. OBRA '87 requires the use of a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity based on a uniform minimum data set for resident assessment and care planning. Federal regulations specify the content of the MDS, resulting in an eight-page form.

Data collected from the MDS now serve as a basis for the following: (1) Medicare & Medicaid certified nursing homes are required to complete a comprehensive assessment upon admission, a quarterly assessment (a form fewer than eight pages is permitted), and an annual re-assessment; (2) Medicare SNFs are required to complete the MDS at specified intervals for payment purposes, thus providing the data necessary to adjust payment rates (a three-page form or the eight-page form for assessments on days 5, 14, 30, 60, and 90 of a Medicare SNF stay is required); (3) All States use the MDS to meet Federal NF requirements related to patient assessment and care planning; (4) Similar to Medicare, some States use the MDS to establish Medicaid payments for NF services; (5) CMS extracts MDS data to develop Federal Quality of Care, and Quality of Life Measures for use as a source of public information; and finally (6) CMS uses MDS data to develop other Federal quality indicators for use in its survey process, which also serves as a source of public information.

In conjunction with the MDS, facilities complete Resident Assessment Protocols (RAPs) for each patient. Originally designed to improve care planning, the RAPs are intended to provide a "road map" from the MDS assessment process to the completion of a thorough, interdisciplinary plan of care. Additionally, the MDS is required to be automated. Typically, after the data are collected on the paper form, facilities enter data into an electronic format. And any changes in the MDS form require new manuals, forms, and training, as well as consultation with States.

Clinical data are often warehoused. For example, MDS data are transmitted to the State Agencies for warehousing, analysis and ultimately, redistribution in aggregate form. A number of States have established, or are planning to establish, separate MDS review programs intended to monitor and assess the accuracy of MDS data for program purposes. States that have implemented these programs and systems have testified to their efficiency and resulting improvement in MDS accuracy and compliance.

The Committee received many comments that the MDS is an unnecessarily complex process that diverts nursing resources to paperwork compliance, and that HHS should streamline the requirements without compromising quality. For example, the Committee heard from a nursing home administrator who recommended that the shorter, quarterly version of the MDS be used for assessments on patients who are "Medicare-only." The quarterly assessment is shorter than the full MDS, contains all of the requisite data for calculating appropriate payment rates, supports the construction of all quality indicators and quality measures required by CMS, and is used on a quarterly basis by Medicare & Medicaid facilities.

The Committee was pleased to learn that CMS has already taken steps to allow the use of a shorter form to gather information needed for Medicare claims. The full MDS will continue to be administered on day 14, consistent with current law and regulation, but a shorter form may be used on days 5, 30, and 90 of a Medicare SNF stay.

In addition, the Committee heard testimony that the MDS is outdated. In particular, the RAPs need to be revised to reflect advances in medical technology. Consulting with patient groups, nurses, physicians, reimbursement specialists, and software vendors would enable HHS to update the MDS so that it becomes a more clinically relevant, effective, efficient, and user-friendly tool. At a time when a nursing shortage exists in the United States, especially in long-term care settings, the Committee believes that it is inappropriate to divert precious patient care resources to unnecessary paperwork. The Committee recommends that the Secretary consider the following MDS changes:

> ***Recommendation:*** **Clarify with interpretive guidance that the MDS is a source document and does not require supporting documentation to justify coded responses.**
>
> ***Recommendation:*** **Adopt a continuous quality improvement process to keep the MDS tool and the Resident Assessment Instrument (RAI) process current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide MDS use (measure work-ups, interpretation of data quality, and interpretation of results, quality reporting, assessment of need for new measures.)**

Recommendation: **Consolidate the number and timing of all MDS assessments to those that are required for care planning purposes, to the maximum extent possible. Refine the timeframes for MDS assessments so that payment and quality cycles coincide and such cycles require the least number of assessments during short periods of time.**

Recommendation: **Follow the General Accounting Office's (GAO's) February 2002 recommendation that CMS not establish its own separate review program, distinct from State efforts, to ensure the accuracy of MDS data for payment purposes. Reorient CMS's proposed MDS accuracy program and confine its monitoring activities to determining the adequacy of each State's efforts to ensure MDS accuracy and providing guidance and technical assistance to individual States, as needed.**

Recommendation: **Encourage SNFs certified to participate in Medicare to use the new shorter assessment form (called the Medicare Payment Assessment Form) to update a Medicare beneficiary's condition on days 5, 14, 30, 60, and 90 of the person's stay in the nursing home. Maintain the policy that skilled nursing facilities complete the full MDS to assess resident status on admission, annually and upon significant change in resident status thereafter. (Note, the requirement that the admission MDS is to be completed no later than l4 days after the resident's admission would continue in force.)**

Overall, the goal of these recommendations is to preserve the intended use of MDS for formulating assessments, plans of care, and quality measurement. With these changes, clinicians will be afforded the opportunity to focus on resident care rather than on paperwork. These recommendations keep essential data elements intact for monitoring quality.

STATE/FEDERAL COORDINATION

"…Just in this calendar year, …we underwent a full [State] Department of Health licensing survey…. Next month, a full Joint Commission survey … the Department of Health then comes in [for a revisit]…. That's a room full of documents that we prepare, and then.… they give us 18 pages of information that they want when they come onsite, and all of this we've done now twice in two months because both the Department of Health and the Joint Commission have deemed status, and many of the regulations overlap…. And then to top it all off, last week we were "fortunate" enough to be chosen for a focused Medicare audit that the Department of Health performed on Medicare's behalf to validate the Joint Commission survey that we had that was a month after the Department of Health survey that surveyed exactly the same information." – Elizabeth Concordia, President and CEO of UPMC Presbyterian and Shadyside, testifying at the Pittsburgh regional hearing.

The Federal government is responsible for ensuring that its expenditures are prudent, and it plays an important role in protecting the health and well being of the nation's most vulnerable

populations. Federal law requires that all facilities seeking participation in Medicare & Medicaid undergo an inspection when they initially enter the program and on a regular basis thereafter. CMS contracts with survey agencies in 54 States and territories to inspect participating providers and determine their compliance with specific Federal health, safety, and quality standards.

The Committee heard testimony on the need for greater coordination between State and Federal agencies on programs that serve individuals who are dually eligible for Medicare & Medicaid. The Program for All-Inclusive Care for the Elderly (PACE) is an example of a program that seeks to better coordinate care for these beneficiaries. PACE aims to provide a better continuum of care, but in doing so, often straddles established provider types. This subjects PACE facilities to multiple reviews and sometimes conflicting requirements. Established PACE programs recommended reviewing duplicative regulations on combination providers and allowing more flexible hiring rules.[5]

Throughout the Committee's deliberations, it became clear that there were opportunities to modify and better coordinate duplicative Federal and State requirements that deflect resources away from patient care. In particular, the Committee recommends the following:

> ***Recommendation:*** **Establish a Task Force to address specific issues related to current practices whereby a single provider or health plan may be reviewed/surveyed/audited by numerous State and Federal entities (especially those under the auspices of the Secretary of HHS), none of which are required to be coordinated. The Task Force should also address regulatory oversight. The task force will be established no later than December 31, 2002, and it will have a six-month time frame for recommendations to be submitted.[6]**

In making these recommendations, the Committee seeks to eliminate duplicative reviews, reduce paperwork burden, and free the resources that would otherwise be devoted to these activities for patient care and quality improvement.

[5] The Committee's work occurred off cycle relative to the Department's actions. The Committee heard testimony prior to the October 1, 2002 Interim Final Rule that establishes a new PACE waiver process and modifies program employment requirements.

[6] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

Master List of SACRR Committee Recommendations [7]
Chapter 2

#	Adopted Recommendations	Full Committee Action
32	Develop shorter versions of the Minimum Data Set (MDS) (e.g., one of the quarterly assessments forms) for Medicare & Medicaid resident assessment to the maximum extent possible. Define the specific uses of any data elements prior to retaining any element on the form as part of an overall streamlining process. Delete or revise all MDS data elements whose reliability is below generally accepted statistical standards.	Adopted May 2002
33	Clarify with interpretive guidance that the MDS is a source document and does not require supporting documentation to justify coded responses.	Adopted May 2002
34	Automate the Resident Assessment Protocols (RAPs) process at the facility level to free-up more time to meet patient care needs.	Adopted May 2002
35	Update the Coverage Manual relevant to Medicare Part A; e.g., who can be covered, authorized benefit periods, breaking the spell of illness and other administrative issues.	Adopted May 2002
36	Integrate updates of the MDS Manual and Resident Assessment [Instrument (RAI)] User Guide and documentation into one manual, distribute the updated guide as soon as possible, and keep the one manual up-to-date. Revise the current manual to incorporate all interpretive guidance and answers to frequently asked questions. Keep a downloadable, up-to-date manual available on the CMS website and publish an annual print edition each year on a set date which incorporates all life-to-date regulation and guidance. Post quarterly updates on interpretive guidance to the CMS website.	Adopted May 2002
37	Continue to develop the MDS 3.0 which will include an analysis of the clinical relevancy of its contents and the capability to capture short stay assessment data, with an expected release date of 2004.	Adopted May 2002
38	Adopt a continuous quality improvement process to keep the MDS tool and the RAI process current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide MDS use (measure work-ups, interpretation of data quality, and interpretation of results, quality reporting, assessment of need for new measures.)	Adopted May 2002
39	Give providers joint property rights to any data submitted as part of the MDS process. [This will allow the provider to access backup copies and may reduce the need for providers to warehouse redundant manual versions of the data.]	Adopted May 2002
40	Develop facility-specific analytic reports that allow facilities to compare their own performance in relation to local, regional and national trends. Develop reports and other tools to share aggregate data with all persons.	Adopted May 2002
41	Shorten the interval from when MDS data were originally collected to when the reports of those data are made public. The older the data are, the less relevant the application and inferences to be drawn from those data.	Adopted May 2002
43	Eliminate data elements that are not used for payment, quality measurement, or survey purposes for those Resident Assessments performed solely for the purpose of complying with Medicare payment requirements.	Adopted May 2002
44	Consolidate the number and timing of all MDS assessments to those that are required for care planning purposes to the maximum extent possible. Refine the timeframes for MDS assessments so that payment and quality cycles coincide and such cycles require the least number of assessments during short periods of time.	Adopted May 2002
52	Seek greater partnerships and outreach to the full continuum of academic medical, nursing, and other allied health care training programs in order to expose all health care professionals (not just specialists) to the value of training in gerontology and participation in interdisciplinary teams, and to the utility of clinical patient care data	Adopted May 2002

[7] An asterisk [*] next to the number of a recommendation indicates that legislative action may be required in order for the Department to implement the Committee's recommendation. See Appendix B.

#	Adopted Recommendations	Full Committee Action
	sets in the process of care planning.	
54	Change the Outcome and Assessment Information Set (OASIS) policies to better reflect actual home health agency (HHA) operations: • Expand the time for completion of the OASIS instrument, for example from 5 days to 7 days. • Change the lock-in time for the OASIS instrument, for example, from 7 days to 14 days. (For example, HHA nurses, especially in rural areas, come to the HHA central office only once a week.)	Adopted May 2002
55	Eliminate separate form for significant change in condition when it occurs in the 5-day window of the follow up assessment.	Adopted May 2002
56	Create the option to use one OASIS form for all situations of care or change in status.	Adopted May 2002
59	Ensure that data collection efforts facilitate development of care plan. • Delete elements that are duplicative or not used for payment (including risk adjustment), quality management, or survey purposes. CMS should particularly scrutinize elements listed in Miami testimony including MO190, MO340, MO640-680, and MO780. • Eliminate OASIS encounters that are not used for payment, quality management, or survey purposes.	Adopted May 2002
61	Adopt a continuous quality improvement process to keep the OASIS tool current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide OASIS use (measure work-ups, interpretation of data quality, interpretation of results, quality reporting, assessment of need for new measures.)	Adopted May 2002
63	Clarify the definition of "significant change." Consider using re-hospitalization as a proxy for "significant change."	Adopted May 2002
64	Conduct an independent evaluation of the cost-benefit of using the OASIS form.	Adopted May 2002
66 *	Seek legislation that would require all insurance companies and other government payers to recognize the validity of the Medicare enrollment process and prohibit them from developing their own processes. [For provider enrollment.]	Adopted May 2002
71	Eliminate [form] HCFA 1513 and HCFA 1514.	Adopted May 2002
72	Incorporate [form] HCFA 2572 into CMS 855.	Adopted May 2002
76	Issue clear directions to carriers and State Agencies (SAs) that observations made on the MDS, OASIS, and other HHS-approved survey instruments do not require redundant manual documentation to support the observations.	Adopted May 2002
79	Adopt protocols for joint ownership of data thus eliminating the need for manual backup copies of data.	Adopted May 2002
80	Establish a task force funded to address specific issues related to current practices whereby a single provider or health plan may be reviewed/ surveyed/ audited by numerous State and Federal entities (especially those under the auspices of the Secretary of HHS), none of which are required to be coordinated. The Task Force should also address regulatory oversight. The task force will be established no later than December 31, 2002 and it will have a six-month time frame for recommendations to be submitted. [8]	Adopted May 2002
99	CMS should eliminate the E&M Documentation Guidelines.	Adopted May 2002 with dissent from Dr. Olsen
100	Encourage skilled nursing facilities (SNFs) certified to participate in Medicare to use the new shorter assessment form [called the Medicare Payment Assessment Form] to update a Medicare beneficiary's condition on days 5, 14, 30, 60 and 90 of the person's stay in the nursing home. Maintain the policy that SNFs complete the full MDS to assess resident status on admission, annually and upon significant change in resident status thereafter. (Note, the requirement that the admission MDS is to be completed no	Adopted June 2002

[8] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

#	Adopted Recommendations	Full Committee Action
	later than l4 days after the resident's admission would continue in force.)	
101	Consider the efficacy of making the collection of OASIS mandatory for Medicare patients only.	Adopted June 2002 with dissent from Dr. Olsen, Mr. Fay, and Mr. Bloom
102*	Establish incentives to encourage State Medicaid programs to discontinue requiring [forms] HCFA 1513, HCFA 1514, HCFA 1561, HCFA 2572 and other forms no longer used by CMS.	Adopted June 2002
108	Follow the GAO's February 2002 recommendation that CMS NOT establish its own separate review program, distinct from State efforts, to ensure the accuracy of MDS data for payment purposes. Reorient CMS's proposed MDS accuracy program and confine its monitoring activities to determining the adequacy of each State's efforts to ensure MDS accuracy and providing guidance and technical assistance to individual States, as needed.	Adopted June 2002
214 *	Issue a Notice of Proposed Rulemaking (NPRM) modifying the enforcement regulation in order to defer the ability of the SA to suspend a facility's nurse aide training programs pending the final results of an appeal; implement the final rule issue required instructional guidance; and provide training to ROs, States and providers.	Adopted June 2002
217	Issue a NPRM modifying 42 CFR § 488.318(b)(2) so that when inadequate survey performance (e.g., "failure to cite only valid deficiencies, failure to use Federal standards, protocols, and the forms, methods, procedures, policies and systems as specified by [CMS]…") is demonstrated/established to have contributed to the citation of a deficiency, that the CMS Regional Office or SA must conduct follow-up (including onsite investigation, if necessary) to validate the presence of the deficiency, if a corresponding remedy is to be applied. Implement the final rule; and require CMS to monitor its application.	Adopted June 2002
230	Issue immediately a written statement that "Medicare hospice providers must recognize the individual's right to self-determination at the end of life and hospice staff should be prepared to provide CPR for hospice patients that request to be resuscitated or do not have a DNR or advance directive."	Adopted September 2002
245	Encourage electronic submission of applications to market new FDA-regulated products, including all relevant information that can be furnished electronically.	Adopted September 2002

CHAPTER 3

IMPROVING COMMUNICATION

> *"Our hope and prayer to the people at CMS (the Centers of Medicare & Medicaid Services) is that you do nothing to weaken the good regulations, that you improve them wherever you can; but certainly we don't want you to weaken them or take them away." – Frances Klafter, age 93, National Senior Citizens Law Center. Public Comment during Minnesota Hearing.*

In this chapter, the Committee highlights another major finding relevant to regulatory reform; namely, that because of fundamental barriers in the manner of the Department's delivery of information, the misinterpretation of the requirements by its agents, or other basic communication failures, the meaning and purpose of rules get "lost in the translation." The Committee believes that better communication is key to easing regulatory burden.

Many problems brought before the Committee are linked in one way or another to the complexity of regulations facing patients and providers, which require additional documents and guidance for implementing the provisions. Compounding this problem, consumers and providers alike often do not know where to get needed information. For example, the Government Accounting Office (GAO) reported in September 2001 that information available from Medicare contractors is not always complete or clear. Answers to specific questions are perceived as inadequate, response to feedback is uneven, and complaints about an unfriendly, even hostile, tone in communications are too common.

Problems are inevitable when people are expected to comply with rules they do not understand. The Emergency Medical Treatment and Active Labor Act (EMTALA) regulations, intended to ensure that patients seeking treatment in hospital emergency rooms receive appropriate screening and care, are a primary example. Complex regulations and uneven enforcement have led to widespread confusion over what the regulations actually require. This confusion in turn has caused resentment and controversy over a regulation that provides an important consumer protection—to provide access to emergency care.

> *"I've wondered since 1993, when I first started as a SHIP (State Health Insurance Assistance Program) advisor, why CMS doesn't approach the military for technical writing? If they, which they do, write documents for 18-year-olds to use in repairing jet engines . . . . then they could certainly help CMS. . ." – E.M. Kevan, Arizona.*

In the past few years, the Department of Health and Human Services (HHS) has begun to address the often unintelligible quality of its communications with consumers, physicians, providers, and health plans. In some areas, such as educational materials for Medicare beneficiaries, these improvement efforts are substantial and are beginning to achieve significant results. In many other areas, however, progress is much less evident.

Eighty three (83) of the Committee's 255 recommendations urge HHS to improve communications. Some recommendations are broad and others highly specific, but the overall

message is clear: HHS and its contractors must speak more clearly, listen more closely, and respond more fully in its communications with consumers and providers.

The Committee urges HHS to develop comprehensive strategies to improve communications overall, to improve access to information, and to improve the quality of that information for both consumers and providers. Since consumers and providers are very different audiences, the Committee has developed different priorities and specific recommendations for improving communications with each.

CONSUMER COMMUNICATIONS

Consumers' information needs vary widely. The Committee heard testimony regarding the necessity of targeting information to meet the specific needs of a variety of populations. Making materials as simple as possible and testing them to make sure they are understandable to the people who need them is key. Special efforts are needed for those who use a different language, or have a different cultural background, or cognitive skills. Information and assistance must be made available in the right places at the right times. For consumers, the Committee's highest priority recommendations focus on the Medicare program and fall into four key areas—Comprehensive Planning, Better Access to Information, Simpler and More Useful Information, and Counseling and Community Partnerships.

***Comprehensive planning*.** The following recommendation identifies consumer communications as a priority for the Medicare program:

> ***Recommendation:*** **Develop, fund and implement a comprehensive, ongoing communications plan that will be coordinated among HHS, CMS and its contractors, as recommended by the HHS's Advisory Panel on Medicare Education, to aggressively reach specific segments of the audience using the appropriate channels including radio, TV, 1-800-MEDICARE, web and print media, as well as other strategies supported by research results.**

***Better access to clear information*.** The Committee finds that Medicare beneficiaries, and those who assist them are often confused by various agencies, offices, and phone numbers that are provided to individuals seeking assistance. Obtaining or understanding the information can be particularly difficult for first time enrollees. The Committee heard through testimony that information provided by the Medicare Compare website and the 1-800-MEDICARE service should be improved. The Committee encourages the Secretary to take specific steps to improve access to information. The Committee urges that the *Medicare & You* Handbook, produced by CMS, encourage Medicare beneficiaries to use the 1-800-MEDICARE number; information provided through the 1-800-MEDICARE number for new enrollees should be reviewed; and to provide an easy-to-locate reminder for Medicare beneficiaries, the Committee makes the following additional recommendation:

> ***Recommendation:*** **Add the 1-800-MEDICARE phone number and www.medicare.gov website address to beneficiaries' Medicare cards.**

The complexity of Medicare program rules and benefits often confuses seniors and makes it difficult for them to navigate the program. Recent flux in the Medicare+Choice (M+C) program,

for example, has concerned seniors who have been forced to adhere to a series of confusing rules in order to switch health plans. The Committee noted that there were many opportunities for the Department to make materials easier to use and understand. The Committee urges HHS to simplify forms, use plain language, and test materials at grade levels lower than its current practice. HHS should evaluate and promote improvements, such as forms that allow people to enroll in more than one assistance program at the same time with one application for all programs, perhaps starting with those under the Secretary's purview, recognizing that this effort will require the cooperation of State and territorial governments. Further, assistance completing applications should be provided for those who need it, and websites that help consumers choose health plans and nursing homes should be improved. The Committee recommends:

> ***Recommendation:*** **Simplify beneficiary forms, use plain language in forms, and use peer focus groups to rigorously re-test the clarity of communication on an ongoing basis. Test the effectiveness of targeting communications literacy to the 4th grade level. (Currently, Medicare policy targets a 6th grade literacy level.)**
>
> ***Recommendation:*** **Simplify the Medicare application using plain language, and encourage States to develop their own simplified, universal application for Medicaid and other services.**

The Committee also notes problems with advance beneficiary notices (ABNs). When a provider is unsure of whether a specific service will be covered by Medicare, and the provider wishes to bill the patient for that service, the provider must provide, and ask beneficiaries to sign, an ABN. The process underlying the need for ABNs should be simplified. More efforts generally should be made to minimize uncertainty as to whether services will be covered. Ideally, Medicare should provide its beneficiaries with prior determinations of coverage.

Finally, the Committee believes that revisions intended to improve materials must themselves be continually reviewed to ensure that they are as effective as possible.

Counseling and community partnership. With thousands of agencies and programs having an impact on Americans in each State, county, and territory, individuals seeking HHS services often find it difficult to navigate the system to find the appropriate program or service. The Committee noted that there were significant communications challenges. In particular, individuals eligible for both Medicare & Medicaid may not be aware of the services provided by both programs. Some Medicare beneficiaries who have low incomes may be entitled to Medicaid coverage that pays for their prescription drugs and all of their Medicare cost-sharing requirements. Others may qualify for more limited Medicaid coverage.

Although some individuals may be concerned about the perceived stigma associated with enrolling in any low-income assistance program, many face significant barriers to accessing necessary information to make informed choice. In fact, large numbers of Medicare beneficiaries are eligible for Medicaid but are not enrolled. The Committee urges HHS to work with States to improve education materials for dually eligible individuals, to better identify dually eligible individuals for purposes of enrollment, and to maximize computerized information systems and "best practices" for identifying dually eligible beneficiaries. The

Committee also believes that community-based organizations could provide assistance to beneficiaries who have language barriers, as well as hard-to-reach eligible populations.

SHIPs are State programs that receive grants from the Federal government to give free health insurance counseling and assistance to people with Medicare. SHIPs train counselors to work with seniors and individuals with disabilities, by answering questions, and help beneficiaries and their families navigate through the Medicare bureaucracy. The Committee examined the SHIPs' efforts and believes that HHS could improve the SHIPs' effectiveness by better integrating them into other beneficiary outreach activities. In particular, the Committee recommends the following:

> ***Recommendation:*** **Improve the accuracy and effectiveness of beneficiary counseling and assistance programs (e.g., SHIPs) by fully integrating them into regional and local outreach activities and by providing consistent training to these programs. Training programs should be based on national standards with implementation tailored to community needs.**

PROVIDER COMMUNICATIONS

Commenters noted that HHS should improve its communications with practitioners, providers, and health plans. Their needs are different from those of consumers. Providers often need highly specific and technical information. Each provider group has unique needs, and there are wide variations in the degree of sophistication and the amount of resources they can devote to understanding and implementing government rules and regulations. For example, a major urban teaching hospital or chain of facilities may have special, dedicated "compliance officers" and other resources to help them understand and comply with regulations that a rural community hospital or small supplier cannot afford. Also, many of the actions needed to improve provider communications involve the fiscal intermediaries and carriers with which Medicare contracts to process claims and educate providers, as well as Medicare beneficiaries. These two audiences may compete for the available educational resources.

Accountability and collegiality. In order to emphasize basic fairness and accountability, the Committee recommends that HHS require its Medicare contractors to report the specific reason when they refuse to pay a claim. Contractors should not merely say a service is "not medically necessary" for instance, but should state the basis for such a conclusion.

> ***Recommendation:*** **Require Carriers and Fiscal Intermediaries to report the specific reasons for their denial of claims in plain language, explain what additional information is needed, and reference the specific regulation, policy memorandum or local medical review policy (LMRP), upon which the denial was based. Appeals to decisions should be reviewed and responded to within 45 days.**

This is one of several Committee recommendations urging HHS and Medicare contractors to be more accountable. For example, the Committee discussed instances when a contractor gave a provider incorrect advice on how to file a claim, and then denied the claim. This led to further discussions about long delays that occur in appealing claims determinations. Consequently, the Committee urges HHS to reduce these delays. Similarly, under current practice, if a skilled

nursing facility (SNF) does not complete the Minimum Data Set (MDS) in the required timeframe, the provider is penalized by receipt of a lower (default) payment while the claim is decided. The Committee heard that these delays are significant for SNFs (paid under the Resource Utilization Group, or RUG, system) and believes that HHS should issue clear and reasonable rules for submission of the MDS and other instruments so that providers are not penalized for legitimate delays in completing the assessment.

> ***Recommendation:*** **Establish an appeal process for default RUG payments with a specified timeframe for the appeal. Establish clear and reasonable rules concerning submission of the MDS instrument so that providers are not penalized with default RUG payments for legitimate, minor delays in completing an MDS assessment.**

The Committee heard from public commenters that the tone of HHS program information issued by Medicare contractors does not consistently convey that providers are colleagues and partners in Medicare's health care delivery system. The Committee believes that all communications must be clear, concise, and collegial in tone. Contractors should collaborate with providers to address systemic and emerging problems and should assume that problems are honest errors best dealt with through targeted education unless there is clear evidence to suggest intentional wrongdoing. HHS should offer more assistance in helping providers learn how to comply with regulations by surveying providers on best practices for complying with regulations and by publishing results for all to see and use.

The Committee also urges HHS to share more information with providers on how systems and policy development processes work. Specific examples include the M+C risk adjustment methodology, and the validity data on the Outcome and Assessment Information Set (OASIS) home health patient assessment form questions. HHS should publicize more widely information about workshops and other opportunities for providers to get training on how to comply with regulations.

Need for consistency and accuracy. Another recommendation for provider communications is to eliminate the practice of individual contractors and CMS regional offices (ROs) rewriting instructions and guidance for providers from CMS headquarters. This is considered a key source of the inconsistency and confusion in Medicare policy that so frustrates providers. The contractors and ROs should rewrite information only when it is necessary due to unique local conditions.

> ***Recommendation:*** **Eliminate the practice of having contractors and ROs rewrite materials from CMS's central office (COs), allowing exceptions only when required by unique local conditions.**

Achieving consistent and centralized information is a common goal of many Committee recommendations. Throughout its deliberations, the Committee noted several additional opportunities for improvements, including the following:

- CMS should ensure that communications are consistent with regulations and monitor contractors to ensure consistent interpretation and application of regulations, program memoranda, and other issuances.

- Contractors should receive regular, ongoing comprehensive training on all Medicare program requirements.
- Contractors, providers, and CMS staff should all have access to the same single, content-controlled database of CMS's program information in order to ensure consistency of answers between contractors, the ROs and the CO.
- CMS should make clear to all its employees and agents the legal difference between "regulations" and "guidance," and the degree to which each is enforceable.
- A central repository of information for providers should be maintained.
- "Best contractor practices" for educating and responding to provider needs should be surveyed and published.
- A workgroup should be established to standardize LMRPs among contractors.

The Committee also finds that there are opportunities to increase consistency between HHS and State agencies' protocols and policy interpretations, such as those regarding the Medicaid program, and surveys of facilities to ensure compliance with regulations. For example, the Committee believes that HHS should use less subjective language for phrases in policy interpretations that historically lead to confusion by the provider community, such as "repeat deficiencies." The Committee recommends:

> ***Recommendation:*** **Improve communication between CMS and States, including the clarity and consistency of Medicaid policy interpretations across CMS, by conducting centralized training for all RO and CO staff to ensure uniformity.**
>
> ***Recommendation:*** **Standardize the investigative protocols of HHS and State survey teams. Increase training for State survey teams. Focus training on the proper interpretation of the regulatory compliance requirements placed on nursing facilities.**

Feedback and comprehensive planning. The Committee notes the merits of surveying providers and using feedback from those surveys to enhance communication. In particular, the Committee recommends that CMS survey providers and other contractor "customers" to determine how satisfied the audience(s) are with the services CMS's agents provide, e.g., in the contractor's processing of claims and providing needed information. This would allow providers, suppliers, and beneficiaries to rate the service they receive from contractors. The Committee notes the value of posting the results of these surveys on the Medicare website and factoring the results into performance ratings when considering contract renewals. The Committee's recommendation further calls for establishing a continuous feedback process for learning about providers' experiences with CMS's agents and incorporating that information into policy and practices. Additional recommendations call for use of focus groups and other means to test communications for effectiveness. To enhance contractor performance, the Committee recommends:

> ***Recommendation:*** **Improve CMS oversight of contractors' customer service performance by establishing a customer satisfaction survey process to be conducted by an organization independent of CMS and its contractors.**

- **Include periodic (e.g., quarterly or semi-annual) survey events along with a continuous customer feedback process.**
- **Individualize approaches for different audiences: beneficiaries, physicians, providers, and suppliers.**
- **Publish customer satisfaction survey results of each contractor in the media and on the CMS and Medicare.gov websites;**
- **Include the results in the contractor performance scores. Use these results in establishing the bidding schedule and as a major consideration in contract awards.**

Indeed, the Committee emphasizes that feedback should be an integral part of all facets of the comprehensive communications plan for beneficiaries and providers. Communication plans should find the most effective ways to incorporate local and national educational campaigns and advisory committees, and focus on listening and responding to beneficiaries and providers. Providers should be involved early in the policy development process. HHS should publish evaluations of its improvements efforts and track progress over time. Another recommendation also focuses on the need to incorporate more feedback from providers.

> ***Recommendation:*** **Enhance provider education efforts by ensuring that comprehensive communication plans are coordinated among HHS, CMS, and its contractors, to aggressively reach the various provider communities (including physician, nurses and other provider groups.) These communication plans should include how to use local and national educational campaigns and advisory committees in the most effective way possible and be responsive to the needs of all provider groups.**

> ***Recommendation:*** **Strengthen efforts to increase and improve provider education on an ongoing basis, with a new emphasis on incorporating feedback from providers into continuous quality improvement efforts. Develop mechanisms to routinely obtain and evaluate such feedback, such as focus groups, surveys, and other methods.**

Better quality information. As with consumer communications, the Committee explored several additional areas to improve the quality of information for providers. The Committee notes that educational materials could be simplified and targeted; formal instructions could be rewritten in plain language and include executive summaries with bullets on key points. In particular, the Committee believes that HHS should evaluate the New Physician Training Manual, along with the websites that provide information on clinical laboratory (CLIA) regulations and LMRPs. The Committee encourages HHS to strive to become a world class supplier of information to providers about the programs it administers, employing the best practices in the industry, against which other insurers can benchmark.

The Committee finds that special efforts are needed in some areas. For example:

- Rural and other providers with limited resources for compliance should receive extra attention.
- Stakeholders should be convened to help revise regulations and guidance for nursing home surveyors and providers.

Policies on other issues should be conveyed in plain language as well. For example, HHS should:

- Clarify when information about individual beneficiaries can be shared with others, such as someone who has power of attorney.
- Clarify policy issuances on all clinical laboratory requirements.
- Address confusion about how nursing home patients can access hospice benefits.

STANDARDIZING COMMUNICATION – HIPAA

A separate new concern brought to the Committee involves communication among providers and payers/health plans. New regulations implementing the Health Insurance Portability and Accountability Act (HIPAA) establish standards for electronic communication of health care transactions, such as sending claims to insurers for payment – a highly technical area. The regulations also set standards for how providers must protect patient privacy. These seemingly separate issues are in fact closely related, now that health care delivery, record keeping, and business are increasingly conducted electronically.

As this trend continues, two principles should be considered: 1) the process for achieving simplification should not be unnecessarily burdensome or costly and 2) with the advent of streamlined technology for transmitting health information comes the responsibility of ensuring that this information is maintained and transmitted confidentially, and that it is not misused. [These issues will be discussed in more detail in Chapter 5.]

Master List of SACRR Committee Recommendations [9]
Chapter 3

#	Adopted Recommendations	Full Committee Action
14	Review and revise the language of its template on Medicare Health Plan Compare in situations where there is a $0 premium or $0 co-pay. The fill-in-the-blank default template language does not make sense for situations where the dollar amount is greater than $0. The result is confusing, misleading and possibly contradictory language as to financial liability.	Adopted May 2002
25	Develop, fund and implement a comprehensive, ongoing communications plan that will be coordinated among HHS, CMS and its contractors, as recommended by the Advisory Panel on Medicare Education, to aggressively reach specific segments of the audience, using the appropriate channels including radio, TV, 1-800-MEDICARE, web and print media, as well as other strategies supported by research results.	Adopted May 2002
26	Continuously improve efforts to educate elderly individuals and/or individuals with disabilities approaching Medicare eligibility.	Adopted May 2002
27	Add the 1-800 MEDICARE phone number and website address to the beneficiary's Medicare card.	Adopted May 2002
28	Eliminate overly burdensome Medicare Secondary Payer requirements.	Adopted May 2002
29	Research, consumer-test and evaluate the current Medicare Summary Notice (MSN) and incorporate those enhancements that result in improved beneficiary understanding of the content. Incorporate reasons for noncoverage or denial of service on MSNs in plain language and refer beneficiaries to relevant regulations regarding the noncoverage or denial.	Adopted May 2002
30	Improve and consistently update the Medicare Plan Finder (which includes original Medicare and Medicare + Choice.)	Adopted May 2002
31	Develop/implement performance standards for CMS's program of beneficiary education and communication efforts so that the program can be implemented consistently by CMS and all its agents and partners.	Adopted May 2002
42	Enhance CMS's investment in education related to the use of the Minimum Data Set (MDS), including web-based training tools such as the Medicare Learning Network. Update the skilled nursing facility (SNF) section of the Medicare Learning Network to include a detailed tutorial on MDS.	Adopted May 2002
45	Add case mix/risk adjustment to quality indicators, as appropriate.	Adopted May 2002
46	Improve the legend of key terms on the Nursing Home Compare website.	Adopted May 2002
48	Improve the balance of nursing home comparative data available for the public to include both quality of life and quality of care measures.	Adopted May 2002
49	Standardize the investigative protocols of HHS and State survey teams. Increase training for State survey teams. Focus training on the proper interpretation of the regulatory compliance requirements placed on nursing facilities.	Adopted May 2002
53*	Establish an appeal process for default Resource Utilization Group (RUG) payments with a specified timeframe for the appeal. Establish clear and reasonable rules concerning submission of the MDS instrument so that providers are not penalized with default RUG payments for legitimate, minor delays in completing an MDS assessment.	Adopted May 2002
57	Share the Outcome and Assessment Information Set (OASIS) risk-adjustment methodology with all users; make the information available on the CMS website.	Adopted May 2002
58	Provide access to the studies on the validity of OASIS data, adverse event measurements, and the University of Colorado study on OASIS quality and outcomes.	Adopted May 2002

[9] An asterisk [*] next to the number of a recommendation indicates that legislative action may be required in order for the Department to implement the Committee's recommendation. See Appendix B

#	Adopted Recommendations	Full Committee Action
109	Improve CMS's oversight of contractor customer performance by establishing a customer satisfaction survey process to be conducted by an organization independent of CMS and its contractors. • Include periodic (e.g., quarterly or semi-annual) survey events along with a continuous customer feedback process. • Include different approaches for beneficiaries, physicians, providers and suppliers. • Publish customer satisfaction survey results of each contractor in the media and on the CMS and Medicare.gov websites. • Include the results in the contractor performance scores. Use these results in establishing the bidding schedule and as a major consideration in contract awards.	Adopted June 2002
124	Examine Social Security Administration (SSA) disenrollment forms and Medicare & You Handbook information to ensure that the text does not stimulate an unintended disenrollment that triggers the "lock-in."[10]	Adopted June 2002
128	Reduce the number of pages of referring telephone numbers in the next publication of the Medicare & You Handbook by focusing on 1-800 MEDICARE so as to avoid overwhelming readers. Ensure that all transferred callers from 1-800-MEDICARE are connected expeditiously with a "live" person at the connected number. Furthermore, work with consumer testing groups to determine the best content and organization of the Medicare & You Handbook, if not currently doing so.	Adopted June 2002
129	Improve communication between CMS and States, including the clarity and consistency of Medicaid policy interpretations across CMS by conducting centralized training for all Regional Office (RO) and Central Office (CO) staff to ensure uniformity.	Adopted June 2002
134	Expand contractual relationships to community-based organizations (in addition to State Health Insurance and Assistance [SHIP] programs, organizations with whom Regional Education about Choices in Health [REACH] currently works) for translation services, information/education services, and outreach to individuals with limited English proficiency, persons with disabilities, and beneficiaries in rural areas. Consider the Request for Proposal (RFP) process as a means of establishing these relationships.	Adopted June 2002
135	Improve the accuracy and effectiveness of beneficiary counseling and assistance programs (e.g., SHIPs) by fully integrating them into regional and local outreach activities and by providing consistent training to these programs. Training programs should be based on national standards with implementation tailored to community needs.	Adopted June 2002
136*	Encourage and/or incentivize State Medicaid plans to provide reimbursement to community agencies providing education and outreach activities.	Adopted June 2002
137	Simplify beneficiary forms, use plain language in forms, and use peer focus groups to rigorously re-test the clarity of communication on an ongoing basis. Test the effectiveness of targeting communications literacy to the 4th grade level. (Currently, Medicare policy targets a 6th grade literacy level.)	Adopted June 2002
138*	Simplify the Medicare application using plain language, and encourage States to develop their own simplified, universal application for Medicaid and other services.	Adopted June 2002
139	Continually evaluate and improve education and communication strategies to ensure that beneficiaries find materials easy to access and understand so they can make informed decisions about their rights, options and obligations.	Adopted June 2002
140	Implement education and training of fiscal intermediaries (FIs) and carrier call centers regarding the rules for disclosing beneficiary-specific information to others (as covered in Transmittal AB-01-87.) Publish these guidelines in plain language for the general public on the medicare.gov website.	Adopted June 2002

[10] This recommendation will be relevant in later years, since the Congress delayed lock-in until 2005.

#	Adopted Recommendations	Full Committee Action
141	Enhance provider education efforts by ensuring that comprehensive communication plans are coordinated among HHS, CMS, and its contractors, to aggressively reach the various provider communities (including physician, nurses and other provider groups.) These communication plans should include how to use local and national educational campaigns and advisory committees in the most effective way possible and be responsive to the needs of all provider groups.	Adopted June 2002
142	Simplify communications to providers using plain language and using formats that are accurate and easy to use by the provider groups on an ongoing basis. Target communications appropriately and include an executive summary of key points in all bulletins, updates, and instructions. (For example, develop a simplified "executive summary" set of instructions for physicians and staff to use the new advanced beneficiary notices.)	Adopted June 2002
143	Maximize the use of technology-based educational initiatives (for example, MedLearn), targeting content to the different types of providers, including non-physician providers, and suppliers of care.	Adopted June 2002
144	Consult with advisory panels or groups of providers to provide real-time review of new communication strategies or materials in a proactive manner. Use focus groups of the intended audiences to rigorously test clarity of communications and educational programs.	Adopted June 2002
145	Ensure that interpretations of regulations are consistent within all manuals and that every program memorandum clearly describes the modifications or introductions of regulations. Require carriers to give answers based on regulations and CMS guidelines and not on their own interpretations. Eliminate penalties or denial of payment to providers for errors due to incorrect advice from carriers or FIs.	Adopted June 2002
146	Continuously improve the development of a central repository of information (i.e., MedLearn) so that general information for providers, and rules/regulations are disseminated from CMS and not individual carriers, while being cognizant of regional sensitivities.	Adopted June 2002
147	Survey FIs and carriers and publicize the results of what are discovered to be the contractors' "best practices" relating to provider education and communication.	Adopted June 2002
148	Compile, publish, and distribute widely a yearly report of provider best practices to serve as guidance for compliance. Give specific emphasis to best practices of rural health programs, clinics or providers among the rural health care community using most effective national and regional outreach methods. Periodically focus CMS teleconferences and listening sessions with various communities of interest on sharing best practices addressing problematic rules and regulations.	Adopted June 2002
149	Ensure that carriers are meeting with the medical community and stakeholders when systemic problems are identified, and that such meetings are used as a basis for provider education programs.	Adopted June 2002
150	Require carriers/FIs to report the specific reasons for their denial of claims in plain language, explain what additional information is needed, and reference the specific regulation, policy memorandum or LMRP, upon which the denial was based. Appeals to decisions should be reviewed and responded to within 45 days.	Adopted June 2002
151	Conduct outreach with the hospice and nursing home industries so that both better understand how Medicare beneficiaries living in nursing facilities can access hospice services.	Adopted June 2002
152	Develop and continuously improve provider educational initiatives programs to address systemic misperceptions and confusion that exist in the home care and long-term care industry about CMS's policies and requirements (e.g., on OASIS, MDS, and "homebound status.")	Adopted June 2002
153	Involve all stakeholders early in the course of policy development to ensure that subsequent regulations and interpretations will be understandable and workable in diverse settings.	Adopted June 2002
154	Assess the effectiveness and publish results of the evaluations of provider educational materials, including but not limited to the new Resident and New Physician Training Manual.	Adopted June 2002
155	Establish a workgroup to evaluate the impact and feasibility of standardized medical review policies.	Adopted June 2002

#	Adopted Recommendations	Full Committee Action
156	Streamline the frequency of communication output, particularly rules and regulations, by ultimately moving to an annual publication of CMS regulations (Medicare Provider Manual) with quarterly updates for new technologies, treatments and coverage decisions. Make this available online and in easy to update paper format.	Adopted June 2002
157	Provide assistance for small rural communities to learn and apply for competitive requests for proposals. Provide account service representatives to rural health clinics/providers.	Adopted June 2002
158	Market/publicize regional technical assistance workshops and train-the-trainer programs to assist rural health care providers and programs in each State.	Adopted June 2002
160	Develop models to educate people from rural communities to become health care practitioners and provide incentives for these practitioners to remain in their own rural communities.	Adopted June 2002
161	Convene focus groups to continue to improve the clarity of the advance beneficiary notice (ABN) for both beneficiaries and providers. Emphasis should include the minimizing of any question of medical judgment.	Adopted June 2002
162	Continue to improve the LMRP web site so it is more user-friendly.	Adopted June 2002
163 *	Evaluate the potential for CMS to develop an automated prior authorization system that could, using computer edits similar to those used by insurance companies in their current claims processing systems, efficiently determine whether most claims will or will not be covered; develop a pilot program to test use of such a system in Medicare; determine the extent to which additional resources beyond computer edits may be needed for accurate prior coverage determinations; implement and evaluate the pilot program, focusing on the benefits perceived by beneficiaries and providers and the potential to minimize costs to the program; and based upon lessons learned in the pilot program, develop and implement a full national Medicare system to furnish prior coverage determinations to both beneficiaries and providers.	Adopted June 2002
165	Simplify and clarify the Clinical Laboratory Improvement Act (CLIA) requirements using plain language whenever possible to assist laboratory and physician office laboratory (POL) staff in understanding and complying with CLIA guidelines.	Adopted June 2002
166	Provide information to POLs about training opportunities by the State survey agencies (SAs) and other accrediting bodies such as the College of American Pathologists (CAP) and the Commission on Office and Laboratory Accreditation (COLA) to assist with interpretation and implementation of new CLIA requirements.	Adopted June 2002
167	Update and make more user friendly CMS's CLIA website; include links to the Centers for Disease Control and Prevention's National Laboratory Training Network.	Adopted June 2002
168	Include a plain language version of both (CDC's) the CLIA requirements as well as a basic laboratory practices document tailored to the POL's test system menu for moderate complexity tests, as part of the CLIA application package.	Adopted June 2002
169	Help laboratories to interpret the new CLIA requirements by offering training and simplified guidelines at meetings of laboratory professionals, accreditation bodies and medical organizations.	Adopted June 2002
170	Develop protocols of compliance surveys for waived POLs that use criteria established in consultation with accrediting agencies and physician organizations. Perform compliance surveys when indicated on waived laboratories according to CLIA guidelines and using criteria established in consultation with accrediting agencies and physician organizations.	Adopted June 2002
171	Modify the Alternate Quality Assessment Survey (AQAS) self survey form as an educational tool to facilitate the survey and certification process.	Adopted June 2002
172	Increase the number of POL representatives serving on the Clinical Laboratory Advisory Committee (CLIAC) to more accurately reflect the number of POLs being regulated.	Adopted June 2002
173	Develop an educational brochure for POLs containing plain language interpretation of the regulatory requirements by having CMS and CDC collaborate.	Adopted June 2002
174	Provide open forums with professional, medical, and accreditation laboratory organizations to solicit feedback on ways to improve outreach to POLs and to increase understanding of the CLIA program among physicians.	Adopted June 2002

#	Adopted Recommendations	Full Committee Action
175	Solicit interest in developing an educational "Clearinghouse" on the CLIA website that includes a multimedia educational program package from interested parties including: CMS, other Federal agencies, professional, medical and accreditation laboratory organizations, and the CLIAC. Design methods for evaluating the effectiveness of educational programs.	Adopted June 2002
176	Collaborate with States and private laboratory organizations to develop and promote self-assessment tools for laboratories, as well as other types of educational programs. Include in these efforts an evaluation of the effectiveness of such educational programs.	Adopted June 2002
177	Stress to CMS staff the importance of collegiality and clarity in communication with providers, and incorporate these factors into employee performance evaluations.	Adopted June 2002
178	Address program integrity problems with a general understanding that most providers want to comply with program rules, and that targeted education is the best way to address problems. Reserve other approaches for instances when targeted education efforts have failed or there is clear evidence of intentional misconduct.	Adopted June 2002
179	Strengthen efforts to increase and improve provider education on an ongoing basis, with a new emphasis on incorporating feedback from providers into continuous quality improvement efforts. Develop mechanisms to routinely obtain and evaluate such feedback, such as focus groups, surveys, and other methods.	Adopted June 2002
180	Ensure that CMS has staff with well-developed talent for explaining complex matters in plain language, and work with policy experts to ensure that written communications to providers are clear, concise, and collegial. Hire and/or train staff extensively to achieve the relatively high skill levels needed to explain complex Medicare policies clearly.	Adopted June 2002
181	Eliminate the practice of having contractors and ROs rewrite materials from CMS's central office, allowing exceptions only when required by unique local conditions.	Adopted June 2002
182	Publish annual reports that establish a baseline and track progress over time of efforts to improve the clarity and collegiality of communications.	Adopted June 2002
183	Evaluate the impact of newly revised materials to determine if they reduce the number of beneficiaries who make inappropriate decisions based on a misunderstanding of their rights and options.	Adopted June 2002
184	Evaluate whether instructing newly eligible beneficiaries to call 1-800-MEDICARE for questions about Medicare Part B eligibility is more effective in helping them to become accustomed to this resource than instructing them to call a toll free SSA online number, which is current practice.	Adopted June 2002
191	Work with States when drafting State Medicaid Letters and solicit States' input prior to the letter being formally issued.	Adopted June 2002
199	Work in coordination with States on development of appropriate educational materials for dual eligibles that are equal in quality to those published for all Medicare beneficiaries, to assist dual eligibles in understanding the programs (including the core set of Federally mandated Medicaid services) to which they are entitled and their financial responsibility in those programs. Use these materials as part of outreach efforts with this population.	Adopted June 2002
200	Evaluate for best practices the State of Connecticut's 211 system for beneficiary information called "Info Line" (www.infoline.org). Determine the extent to which other States are using this model and encourage the use of systems like "Info Line" by States as a model for all Medicare & Medicaid beneficiaries.	Adopted June 2002
201	Clarify in the State Operations Manual (SOM) section(s) dealing with "Medicare-Medicaid Certification – Distinct Part Designation", that any reference to particular "examples" (mentioned either in relevant Instructions, Survey Procedures, Interpretive Guidelines, or Forms) is intended only to be EXEMPLARY of how compliance may be achieved, but does not constitute the only configurations that are allowed for compliance with the statute or regulations. Clarify for State surveyors, that in the absence of a facility complying with one or more examples that are mentioned, the facility must still be able to demonstrate how it complies with the regulation or statute. Provide guidance and training to surveyors and providers. Follow-up and monitor consistency in application. (Recommendation refers to just SNF/NFs.)	Adopted June 2002
202*	Require FIs to render decisions on demand bills within 45 days after receiving all medical	Adopted June

#	Adopted Recommendations	Full Committee Action
	records documentation required by the FI to support the original decision made by the SNF. If the FI decision is not rendered by 90 days, require FIs to pay the SNF automatically. Require administrative law judges (ALJs) to render a decision within a 90-day period of time after an appeal is filed at the ALJ level. Allow payment without "prejudice" during the appeals period.	2002
204	Provide comprehensive training, as opposed to broad based generalized training, for carrier and FI telephone customer service representatives (CSRs) so that CSRs are more knowledgeable in specific areas, and can improve their level of consistency in providing answers. Consider the merits of credentialing some or all of the contractors' CSRs in order to ensure that issue experts can directly respond to specific provider inquiries.	Adopted June 2002
205 *	Convene relevant stakeholders to work with CMS to: • reconcile conflicts in regulations and/or guidance that prevent clear delineation as to which entity (the SNF or the hospice) is required to be the lead in providing required end-of-life care to SNF residents once they elect their hospice benefit; • revise guidance and procedures to recognize end-of-life care in the context of the survey protocol and the SNF/NF's operations under each individual agreement with hospice; and • define the precise, unambiguously stated conditions under which, terminally ill beneficiaries who are residents of SNFs/NFs, may access their statutorily entitled hospice benefit. Incorporate these revisions and criteria-based conditions into the SOM as part of interpretive guidance for surveyors of hospice and SNFs/NFs, at Task 6, K., at other relevant sections of the Guidance to Surveyors, as well as into relevant Program Integrity Instructions that ultimately affect the ability of hospice and SNFs/NFs to provide these services. Reconvene all relevant stakeholders to determine if more structural changes are needed, based on the degree of success achieved by the newly issued guidance. If necessary, revise and incorporate changes (including criteria developed from above) to the CMS conditions for participation for both hospice and SNFs/NFs in order to assure that beneficiaries may access their statutorily entitled benefits and the appropriate entity can be held accountable. Implement final rule and provide training to both hospice and SNF/NF surveyors and providers.	Adopted June 2002
206	Issue a revised policy declaring that due to the national nursing shortage, we are in a period of "extraordinary circumstances." Due to this problem, contracting for nursing services for continuous care is allowed. The statement should restate the responsibility of hospice when contracting for services, located in 42 CFR § 418.80.	Adopted June 2002
207	Convene relevant stakeholders to work with CMS to revise the threshold definition of "harm" as applied in the SNF/NF enforcement process, and operationalize item-specific criteria for decision making at each relevant survey requirement. Publish the results of this collaboration in a Notice of Proposed Rulemaking (NPRM) and revise relevant regulations, as needed. Implement the final rule; develop guidance for survey and enforcement; provide training to surveyors and providers; and require CMS to monitor its application by surveyors.	Adopted June 2002
208	Convene relevant stakeholders to work with CMS to amend the threshold definition of "repeat deficiency" as applied in the SNF/NF enforcement process; insure that the more serious remedy associated with a repeat deficiency can only be applied in the presence of a repeat occurrence of the same problem, and/or a repeat deficiency of the same subordinate requirement within the larger regulatory group. (For example, under the larger regulatory grouping, "Quality of Care," there might be a citation related to wound care on one survey, and a citation related to personal grooming, found on a subsequent survey. For purposes of the Advisory Committee's recommendation, the latter citation would not constitute a "repeat deficiency" of wound care, and hence the more serious penalty would not be imposed.) Issue a NPRM adding the revised definition from above at 42 CFR § 488.401 and related requirements, as needed; publish a final rule; develop and issue corresponding instructional guidance in SOM Chapter, 7, Section 7516, and (C) (3). Provide training to surveyors and providers; require CMS to monitor its application by surveyors.	Adopted June 2002

#	Adopted Recommendations	Full Committee Action
209	Convene relevant stakeholders to define and clarify the criteria for when a determination of a "quality of care" deficiency rises to the threshold level of "abuse and neglect." Publish a NPRM incorporating these criteria and related requirements; amend the SOM Guidance to include and implement these new definitions; and provide training to ROs, States, and providers.	Adopted June 2002
212	Strengthen the quality of SOM communications (e.g., survey procedures, interpretive guidance, written instructions, etc) written for the primary audience of SAs and surveyors, by infusing it with a more positive, less provider-adversarial tone and stance. Include specific instructions and guidance that suggest or favor increased communication between surveyors and providers, including allowing surveyors to exchange information with providers on best or innovative practices. Design training programs for surveyors and providers that implement these types of less adversarial, more collegial types of changes.	Adopted June 2002
216	Convene relevant stakeholders to modify and operationalize the definition of "substandard quality of care" and defining the exclusive set of the subordinate requirements/survey tags whose citation can constitute the threshold determination of substandard quality of care (i.e., only those requirements that deal with the provision and quality of care, and/or to the training of nurse aides, but NOT to the citation of other SNF/NF requirements, e.g., having sufficient closet space, etc.) Issue a NPRM to this effect; publish and implement a final rule; issue revised instructional guidance; provide training to the surveyors and providers.	Adopted June 2002
218	Issue a NPRM modifying the regulation at 42 CFR § 488.331 to include criteria for "timeliness" (so that it applies to timely transmission of both the CMS Form 2567 [Statement of Deficiencies] and the notice to the facility of its opportunity to request an Informal Dispute Resolution [IDR].) Until such time as a regulation can be promulgated, issue instructional guidance to State and Federal survey agencies establishing preliminary criteria for timely response to IDR requests. Implement final regulation; and provide guidance and training to ROs, States and providers.	Adopted June 2002

CHAPTER 4

INCREASING FLEXIBILITY

> *"…We have been a local marketplace success.... We've had health plan interest and provider interest in expansion. Consumer satisfaction has been high....we need to develop some clear templates to make it easier for States and providers to pursue these integrated demonstrations..." – Pam Parker, Panelist discussing PACE, Minneapolis Hearing – June 2002.*

Health care regulation must adapt to changes in health care technology and changing relationships within the system. Marketplace innovation offers patients, physicians, hospitals, other providers, suppliers, and health plans opportunities to improve health and allow individuals to live longer and happier lives. Programs that require Federal and State government coordination, such as Medicaid, add a layer of complexity that makes it particularly challenging to deliver care. Layers of statutory requirements, Federal program directives, and implementing judicial decisions compel providers to redirect significant resources from the provision of care to unnecessary paperwork and other time consuming activities.

The Committee heard concerns that the implementation of program requirements often results in limited flexibility for patients, providers, and other business partners. While regulation plays an important role in protecting consumers, regulations, mechanically enforced, can stifle innovation in service delivery and quality improvement. Regulators should think not only about achieving policy objectives, but also about the process required for the rule to be implemented. For example, regulators should consider what changes in information systems will be needed, or how a new required activity fits with current provider work processes or patient flow patterns. Once a rule is in place, regulators should evaluate its effectiveness. Did the rule produce the desired outcome? At what cost? What operational problems or unintended consequences emerged, and how could they be addressed? Over time, do changes in the marketplace, the organization and delivery of medical services, or beneficiary needs make some rules obsolete or suggest the need for revision?

IMPROVING IMPLEMENTATION

The Committee received testimony outlining problems with the Department of Health and Human Services (HHS's) implementation of statutory requirements throughout its deliberations. The Committee heard concerns about the cost-benefit analyses used to support previously issued rules. For example, many commenters stated that the initial Health Insurance Portability and Accountability Act (HIPAA) Transaction and Privacy Rules were promulgated based on impact statements that underestimated the full cost of compliance. While they agreed that long-term savings would likely be realized, the initial costs of compliance will adversely affect many providers and plans. This impact is particularly difficult for those providers and health plans operating under constrained reimbursement, which limits the funds available to comply with regulations. In addition, the Committee finds that, in many cases, interpretive guidance does not reflect cost estimates for compliance. The development and release of Home Health Agency

(HHA) survey and certification guidelines and Medicare+Choice (M+C) operational policy letters are two examples.

Regulations often create administrative inefficiencies that can have an adverse impact on both consumers and providers. For example, Medicare is able to require all HHAs to use a standard patient assessment data collection instrument (OASIS) on all clients regardless of whether the patient has private insurance coverage, Medicaid, or Medicare, because OASIS is a requirement contained within the Conditions of Participation (COPs) for Medicare HHAs. OASIS is an example of the process-oriented requirements found in COPs, Medicare's basic health and safety standards.

In contrast, an oversight system focused on outcome-based quality standards can retain both structure and process requirements, but compliance is monitored less frequently for certain providers or health plans. The rationale for this approach would be evidence of sustained good performance by those providers or plans. For private health plans that could otherwise demonstrate compliance with regulations and quality standards, this could mean alternatives such as the use of data-driven and focused review-based monitoring visits to determine compliance with Medicare's regulations. The end result would be a reduction in the multiplicity of reviews and the ability to redirect scarce resources for the benefit of a plan's enrollees.

MULTIPLE REVIEWS

Multiple reviews and audits of the same provider or health plan by different oversight agencies demonstrate the burdensome nature of multiple regulatory requirements. State and Federal governments, as well as private sector employers, are increasingly interested in collecting quality data. As a result, many managed care organizations are now audited repeatedly for administrative data and asked for significant amounts of information on adherence to preventive care guidelines and other care algorithms. Several private sector organizations conduct quality reviews, including the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA). Other groups also collect quality data, including Medicare's Quality Improvement Organizations (QIOs) and some professional societies. Despite efforts at coordinating data collection elements and their definitions among the various groups, little congruence exists among the expectations of the groups. The Committee heard through comment and testimony that each reviewer's requests are complex, and each review typically requires that information be presented in a specific way.

This lack of coordination is problematic, particularly because entities may be faced with largely redundant requests for information several times a year. Realistically, no health care organization can launch measurement and improvement initiatives in all of these areas at the same time. For example, the disparate requests by the various regulators may overwhelm quality programs in hospitals. The large number of quality measures, combined with the lack of consensus as to their validity, undermines effectiveness of all the efforts. Those responsible for quality measurement and improvement in individual hospitals or physician groups are forced to choose which regulatory mandates to comply with and which to ignore. This number of requests could also potentially inhibit providers' ability to implement quality improvement initiatives tailored to their unique local situations.

Moreover, once the burden of regulation becomes overwhelming, the legitimacy of the regulatory enterprise may be questioned, and cynicism and resignation may be fomented among healthcare providers. A second concern may be even more important. The creation of multiple uncoordinated mandates regarding quality measurement and improvement means that hospitals incur substantial additional costs in responding. Responding fully to the reporting requirements suggested by the JCAHO and consensus organizations, such as the National Quality Forum, is very time-consuming. For hospitals, this often means that larger investments in quality measurement and reporting must be made with insufficient evidence that the particular activity improves quality.

The Committee heard similar concerns from HHAs and nursing facilities. At a time when providers are constraining their costs in response to reimbursement pressures, they are also required to expand their investment in reporting data related to a variety of quality measures. As the regulatory bodies make these data available, providers will undoubtedly need to spend additional human and financial resources to assess the results and respond publicly prior to initiating any improvement programs.

The Committee heard from health care organizations, including health plans and hospitals, that government agencies should make greater use of "deeming," by which approval by private organizations such as the JCAHO and the NCQA is accepted to satisfy government requirements. For example: CMS Regional Office (RO) staff conduct oversight of both M+C health plans and deeming organizations certified to accredit plan participation in Medicare. The Committee heard suggestions for how to alleviate the burden caused by multiple reviews, including: coordinating the review schedules between agencies so that health care organizations can provide information in a common format and less frequently; requiring that reviewing agencies make better use of electronic data submissions; and concentrating reviews on "bad actors."

The Department can take specific action to improve the implementation process for regulations. For example, CMS could minimize the unique challenges faced by rural providers (described in Chapter 1) by taking a more rational approach to survey and certification activities. Today, a critical access hospital (CAH) may provide a variety of services (e.g., home health, skilled nursing, inpatient acute care) and be surveyed separately for each of the different types of services it provides. To reduce the impact on CAHs, CMS could conduct a single survey of a CAH to certify compliance with all relevant program standards that apply to the home health, skilled nursing, and inpatient acute care it provides, thus saving the resources the CAH would have to devote to this activity and recognizing the integrated nature of the care provided.

Likewise, CMS now separately: performs an on-site visit to review a Medicare+Choice organization's (M+CO's) activities for compliance with Federal requirements as laid out in CMS monitoring guidelines; conducts an audit to verify the M+CO's annual rate and benefit filing; and reviews records to verify encounter data submitted for risk adjustment. Audits and monitoring are necessary to ensure an M+CO's compliance with statutory requirements. However, CMS's fragmented approach to site visits is overly burdensome, requires duplicative preparation, and increases costs. Alternative options for determining plan compliance should be pursued. Based on these findings, the Committee recommends the following:

Recommendation: **Establish a coordinated annual schedule for CMS-related on-site audits/reviews of M+COs to ensure that oversight activities are coordinated to the greatest extent possible for those M+COs that wish to have their routine periodic and scheduled reviews take place at the same time. (Unannounced reviews or visits would not be affected by this provision.)**

HOME HEALTH AGENCIES

HHAs provide Medicare covered services to approximately 2.5 million patients per year, and provide an average of 36 visits to each patient. Reimbursement for Medicare home health totals approximately $12.2 billion for fiscal year 2002. The Committee heard testimony that HHAs participating in Medicare need more flexibility in the management of their operations to better serve their patients. The Committee believes that the home health COPs do not reflect the use of current technology nor modern management. Revised COPs for HHAs have not been finalized since they were proposed in 1997 (except for those specifically related to collection, encoding and transmission of OASIS.) The Committee recommends the following:

Recommendation: **Publish a final rule on the previously proposed rule on Conditions of Participation (COPs) for Home Health Agencies (HHAs) currently in the queue.**

CMS provides guidance to State government (SA) surveyors who act on behalf of the Department. The surveyors review HHA operations to ensure the agency meets Medicare's COPs. The guidance to State surveyors specifies the process requirements HHAs must meet in order to deliver home health services. In addition, the COPs set parameters on the operational structure for any separate home health entity delivering services not covered by Medicare (e.g., separate admissions policies, clinical records and personnel records, etc.). For many HHAs, Medicare's interpretive guidance for survey and certification staff serves as an additional layer of regulation, and constrains their ability to offer consumers the non-Medicare products they desire, such as private duty nursing and custodial care. Medicare should consider regulatory standards that could be adjusted for small providers or for those with a limited Medicare caseload. The Committee recommends that HHAs should have greater flexibility.

Recommendation: **Limit application of Medicare's Home Health COPs based on certain payers (e.g., apply to Medicare patients only) and service criteria (e.g., the criteria would exclude services that do not meet the definition of "home health services" in the Social Security Act, Section 1861, such as those that are custodial in nature or considered personal care and may not result from a signed physician order.)**

Recommendation: **Revise the CMS Interpretive Guidance on Medicare's HHA COPs (the State Operations Manual [SOM]-Provider Certification, Section 2183, "Separate Entities") to give all agencies more flexibility in managing their operations, such as the requirements for separate policies and procedures for admission, separate clinical records, separate licensure (unless required by State), separate time sheets and personnel records, and separate budgets. (The Interpretive Guidance contains directions to State**

surveyors, for recognizing and qualifying an organization as a "separate entity" so that they can properly certify that a HHA meets Medicare COPs. The surveyors would not apply the COP requirements to the patients served by the "separate entity.")

MEDICARE+CHOICE

Congress established the M+C program in 1997 to provide seniors and Americans with disabilities a choice of private health plan options similar to those offered to the under-65 population. Today, approximately 4.9 million seniors are enrolled in a M+C plan. The regulations that govern M+C exemplify the Committee's concerns about rigid interpretations of the law. Beneficiary enrollment and health plan participation in the program peaked in 1999. As a result of health care costs climbing faster than M+C payments, along with other factors, enrollment in M+C plans fell as plan participation declined.

To help beneficiaries remain in their plan, CMS undertook a series of initiatives to enhance provider network stability by reducing administrative requirements that divert resources away from health plan benefits and services. The Committee has identified several important areas in which CMS can make further improvements to M+C requirements, such as the review of marketing materials intended for beneficiaries, data filing requirements for health plan benefits and rates, and payment reconciliation, as well as standards for determining compliance with Medicare's regulations. Medicare should implement solutions to mirror those in the private sector that can streamline and speed administrative activities for beneficiaries, health plans, and providers. [Some technological solutions are discussed in Chapter 5.]

M+COs are required by statute to submit all M+C marketing materials and enrollment materials to CMS at least 45 days before they are to be disseminated. This allows CMS to determine whether marketing materials contain adequate information about certain topics and whether they contain materially false or misleading information that could induce a beneficiary to enroll in (or remain enrolled in) an M+C plan or cause a plan enrollee to fail to exercise his or her rights to receive covered benefits. CMS does provide M+COs with a 10-day review period if they follow certain CMS models without modification.

The Committee heard assertions that reviews requiring the full 45-day period frequently result in substantial delays in the availability of accurate information. Some M+COs noted that CMS ROs may require revisions for editorial or stylistic reasons, even though these M+COs believe that the materials are not misleading or inaccurate and do not contain misrepresentations. CMS should continue to protect beneficiaries from receiving misleading marketing materials but ensure that they receive timely information. In response to these comments, the Committee makes the following recommendation:

Recommendation: **Continue to standardize and streamline the process of receiving M+CO marketing materials, including nationwide use of "use & file" standards; establish uniform performance standards that do not exceed statutory requirements and provide training prior to their use by all CMS ROs.**

To participate in the Medicare+Choice program, M+COs annually submit a rate and benefit package (an Adjusted Community Rate Proposal or ACRP.) The ACRP was established to ensure that the monthly rates charged by M+COs are justified by the benefit package offered to beneficiaries and that the rate and benefit package is commensurate with the CMS payment. Many M+COs offer different benefit packages within segments of their service area and must submit separate ACRPs for each M+C plan they offer. The ACRP was revised several years ago, but it still requires information that may not add to the actuarial soundness of the filing, nor meet the sound actuarial standards required in similar commercial, private sector filings. The ACRP filing process requires unnecessarily detailed submissions in some cases, and redundant submissions in others when plans serve multiple markets. The Committee recommends the following:

> ***Recommendation:*** **Simplify the Medicare program's data filing process requirements in ACRPs for M+C health plans; prepare a report due September 30, 2002 to inform that goal which examines the following options:[11]**
>
> - **Statutory recommendations that would allow plans to use M+C only data in doing their ACRPs;**
> - **Allow M+COs to make greater use of actuarially-generated information rather than information from the accounting systems in the ACRPs;**
> - **Reduce the number of filings for the 2004 filing;**
> - **Reduce the back-up documentation required for the 2004 filing;**
> - **Use simpler filing forms similar to those used in State Department of Insurance filings; and**
> - **Reduce the number of benefit categories submitted in the ACRPs for the 2004 filings.**

Because of the lack of effective interfaces among State and Federal agency information systems, the process for making determinations of M+C enrollee status is time-consuming, resource intensive and regularly results in extensive delays in remitting substantial retroactive payments to M+COs. M+C payments are adjusted to reflect a variety of patient characteristics. For example, the private health plans receive a payment adjustment for each enrollee who continues to work and is covered by an employer plan, or is diagnosed with end-stage renal disease. Adjustments are also made on the basis of the country, in which the enrollee resides, and the enrollee's age and institutional status. CMS uses multiple information systems to determine enrollee status. Payments to M+COs must be adjusted monthly based on enrollee characteristics that reflect differences in the cost of providing covered benefits. M+COs are responsible for verifying and reconciling CMS's information and the plan's information to ensure payment accuracy.

The Committee heard that a more timely and efficient system for payment reconciliation would encourage M+COs to remain in the program and would contribute to program stability. In addition, the Committee discussed alternative methods for determining a plan's compliance with Medicare regulations. For example, the Committee suggested that those established plans with good performance might not require the same intensity of review as new plans, or those with

[11] This date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

declining enrollments. In response to these comments, the Committee makes the following recommendations:

> ***Recommendation:*** **Determine new procedures for processing working aged enrollments for M+CO payment reconciliation purposes and establish a pilot (to test the new procedures). Analyze systems issues with End Stage Renal Disease (ESRD) enrollments of individuals with and propose workarounds.**
>
> ***Recommendation:*** **Convene a work group whose goal is to pursue alternative methods of determining a M+CO's compliance with Medicare's regulations, such as by data-driven and "focused review"-based biennial monitoring visits. (Plans with good performance should not be subject to total review.) Implement work group's recommendations not later than January 1, 2004.**[12]

Similarly, risk-adjusted payments are designed to more accurately pay M+COs based on demographic information, certain special enrollment status codes and the health status of the beneficiary. During the development of the health status-based risk adjustment method for the M+C program, CMS made a decision not to implement risk adjustment in a budget neutral manner within the M+C program. The Committee was concerned that the implementation plan for risk-adjusted reimbursement will adversely affect provider network stability, and thus the willingness of plans to continue operating in their current service areas. Therefore, the Committee recommends that CMS implement risk adjustment in a budget neutral manner.

> ***Recommendation:*** **Make the changes necessary to implement the M+C enrollee health risk adjustment methodology with the M+C program on a budget neutral basis, without increasing or decreasing total funding for the M+C program as intended by Congress.**

STATE FLEXIBILITY

The success of Federal-State health program partnerships is dependent on the flexibility of each partner in the relationship. Medicaid, a jointly funded Federal-State health program operated by State governments, is a prime example. CMS conducts oversight of State Medicaid programs through its regional offices. Innovative program changes at the State level must be approved through a waiver process that, until recently, was lengthy and burdensome, even if other waiver States were successfully implementing identical programs. "Dear State Medicaid Director" letters, generally used to inform States about significant changes in Federal policy, have the potential to disrupt a State's programs and relationships with Medicaid providers. Shifting from heavy-handed regulation to demonstrated outcomes-based processes would change the Federal role to one of partnership with the States and foster innovative solutions. To allow public programs to keep pace with fast-changing health care services and changing populations, the Committee recommends the following:

[12] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

> ***Recommendation:*** **Give States greater flexibility in developing their programs by stating the purpose of the program (for example, providing health care to individuals with low incomes) and giving the States the ability to design their own program, in compliance with Federal law, while holding States accountable for achieving the outcomes in accordance with pre-established criteria. (Do not specify how States should meet those criteria.)**

States, seeking creative solutions to serve dually eligible individuals who are elderly or who have disabilities, often focus on coordinating service delivery and satisfying the desire for community-based care. These creative approaches face the obstacle of the budget neutrality requirement imposed by the Social Security Act. When the Federal government analyzes the cost-effectiveness of a Medicaid waiver, it measures the cost to the Medicaid program itself and does not measure the costs across all benefit programs under the purview of the HHS.

As the Committee considered the waiver issue, it was suggested that the Federal government's definition of "cost-effective" be defined as providing services under a waiver in a manner that will cost no more to the combined Medicare & Medicaid programs than the cost of providing the same (or better) Medicare & Medicaid services separately on a fee-for-service basis to the same population. The Committee notes that integration and coordination of many Federal and State programs could increase the quality of care and provide savings. For example, at a field hearing in Minneapolis, a panelist noted that the integration of Medicare & Medicaid dollars, along with the flexibility to develop care plans based on the frail older adult's needs instead of rigid Medicare or Medicaid guidelines, allows her PACE (Program for All-Inclusive Care for the Elderly) organization to improve the quality of care and to deliver more cost effective care and care plans. In particular, the panelist noted that the waiver enhances the staff's ability to intervene quickly and begin treatment in a few hours in what could take a few days to a few weeks in the traditional system. The Committee responds with the following recommendation:

> ***Recommendation:*** **Work with the Office of Management and Budget to recognize that budget neutrality is measured across Medicare and all benefit programs under the purview of the Secretary of the Department of Health and Human Services, not solely Medicaid. A specific situation to apply the recognition is when determining whether waiver services are cost-effective, CMS should uniformly clarify or adopt the policy that "cost-effective" means waiver services will cost no more to the Medicare & Medicaid programs combined than the combined costs of providing Medicare & Medicaid services on a fee-for-service basis to the same population.**

The Committee makes these recommendations with the objective of improving the implementation of policy objectives without stifling innovation or quality improvement.

Master List of SACRR Committee Recommendations[13]
Chapter 4

#	Adopted Recommendations	Full Committee Action
1	Publish a final rule on the previously proposed rule on Conditions of Participation (COPs) for home health agencies (HHAs) currently in the queue.	Adopted May 2002
2	Announce removal of the Proposed Rules on HHA COPs from the docket if the proposed rule remains dormant for more than six months from the date of adopting this recommendation.	Adopted May 2002
3	Eliminate or modify the definitions of branch office and sub-unit contained within Medicare's COPs for HHAs to reflect current technology and accepted practices.	Adopted May 2002
4	Allow Medicare + Choice Organizations (M+COs) to access State and county codes, and input changes to that data element during the summer of 2002 for payment reconciliation of special status Medicare enrollees. (Direct access to proprietary information held in Federal databases would be limited in accordance with the Privacy Act.)[14]	Adopted May 2002
5	Determine new procedures for processing working aged enrollments for M+CO payment reconciliation purposes and establish pilot. Analyze systems issues with ESRD enrollments and propose workarounds.	Adopted May 2002
6 *	Simplify the Medicare program's data filing process requirements in Adjusted Community Rate Proposals (ACRs) for M+C health plans; prepare a report due September 30, 2002 to inform that goal which examines the following options: • Statutory recommendations that would allow plans to use M+C only data in doing their ACRs; • Allow M+COs to make greater use of actuarially-generated information rather than information from the accounting systems in the ACR; • Reduce the number of filings for the 2004 filing; • Reduce the back-up documentation required for the 2004 filing; • Use simpler filing forms similar to those used in State Department of Insurance filings; and • Reduce the number of benefit categories submitted in the ACR for the 2004 filings.[15]	Adopted May 2002
7	Provide additional comprehensive training for auditors concerning the development of ACR proposals in order to decrease the occurrence of erroneous and incorrect findings; include industry experts in the faculty for the training sessions. Consult with industry experts in the design of the training.	Adopted May 2002
8	Convene a work group whose goal is to pursue alternative methods of determining a M+COs compliance with Medicare's regulations, such as by data-driven and "focused review"-based biennial monitoring visits. (Plans with good performance should not be subject to total review.) Implement work group's recommendations no later than January 1, 2004. [16]	Adopted May 2002
9 *	Continue to standardize and streamline the process of receiving M+CO marketing materials, including nationwide use of "use & file" standards; establish uniform performance standards that do not exceed statutory requirements and provide training prior to their use by all CMS Regional Offices (ROs).	Adopted May 2002

[13] An asterisk [*] next to the number of a recommendation indicates that legislative action may be required in order for the Department to implement the Committee's recommendation. See Appendix B.

[14] This date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[15] This date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[16] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

#	Adopted Recommendations	Full Committee Action
10	Establish a policy wherein joint training is conducted for M+CO CMS Regional Office (RO) and Central Office (CO) staff in one setting regarding major initiatives and issuance of significant changes in existing M+C policy.	Adopted May 2002
11	Establish a policy to provide sufficient notice to M+COs to implement major CMS information systems' changes allowing M+COs to adequately budget for said changes, many of which occur when M+COs are in the midst of implementing other statutory system upgrades, such as Y2K and HIPAA.	Adopted May 2002
12	Establish a Special Election Period (SEP) for current M+CO members who wish to enroll in a zero-premium plan offered by the same M+CO in 2002 consistent with the "lock-in" requirement.[17]	Adopted May 2002
13	Establish a policy that allows M+C plans to default members to replacement plans based on the member's primary care physician choice.	Adopted May 2002
15	Clarify the 36-month payment reconciliation rule to ensure that the 36-month window runs from the time an M+CO submits its information or claim rather than the time CMS acts on and enters the information or claim into the system.	Adopted May 2002
16	Publish regulations in a timely fashion. States are left in limbo or held financially responsible for unclear policies. [For example, finalize and publish the newest revision of *Medicaid and School Health: A Technical Guide* for States; clarify the policy related to payment for these services. (The "Old" version of the *Technical Guide* still references Medicaid as a payer of last resort for health-related services. [The transmittal of May 2000 indicates the opposite.])	Adopted May 2002
62	Field test new the Outcome and Assessment Information Set (OASIS) measures before they are put into use.	Adopted May 2002
120 *	Limit the application of the Medicare's Home Health COPs based on certain payers (e.g., apply to Medicare patients only) and service criteria (e.g., the criteria would exclude services that do not meet the definition of "home health services" in the Social Security Act, Section 1861, such as those that are custodial in nature or considered personal care and may not result from a signed physician order.)	Adopted June 2002 with dissent from Dr. Olsen
121	Revise the CMS Interpretive Guidance on Medicare's HHA COPs (the State Operations Manual – Provider Certification, Section 2183, "Separate Entities") to give all agencies more flexibility in managing their operations, such as the requirements for separate policies and procedures for admission, separate clinical records, separate licensure (unless required by the State), separate timesheets and personnel records, and separate budgets. [The Interpretive Guidance contains directions to State surveyors for recognizing and qualifying an organization as a "separate entity" so that they can properly certify that a home health agency meets Medicare's COPs. The surveyors would not apply the COP requirements to the patients served by the "separate entity."]	Adopted June 2002 with dissent from Dr. Olsen
122*	Establish a coordinated annual schedule for CMS-related on-site audits/reviews of M+COs to ensure that oversight activities are coordinated to the greatest extent possible for those M+COs that wish to have their routine periodic and scheduled reviews take place at the same time. [Unannounced reviews or visits would not be affected by this provision.]	Adopted June 2002
123	Establish a process for making timely changes to the standardized Summary of Benefits (SB) language so that beneficiaries can rely on it to make informed choices. Permit limited variations from the standardized language when they are needed for accuracy and are made in a way that does not undermine the utility of the SB for plan-to-plan comparison.	Adopted June 2002
127	Make the changes necessary to implement the M+C enrollee health risk adjustment methodology with the M+C program on a budget neutral basis, without increasing or decreasing total funding for the M+C program as intended by Congress.	Adopted June 2002 with dissent from Ms. Ryan, Mr. Fay, Ms. Pattee, Dr.

[17] This recommendation will be relevant in later years, since the Congress delayed lock-in until 2005.

#	Adopted Recommendations	Full Committee Action
		Olsen and Ms. Martin
130 *	Seek administrative solutions within statutory parameters to reduce Transitional Medical Assistance (TMA) reporting requirements from quarterly to annually until such time as the statutory parameters are addressed. [Currently, families receiving transitional Medicaid coverage must report requested information quarterly, and they lose eligibility if the information is not submitted.]	Adopted June 2002
189	Work with OMB to recognize that budget neutrality is measured across Medicare and all benefit programs under the purview of the Secretary of the Department of Health and Human Services, not solely Medicaid. A specific situation to apply the recognition is when determining whether waiver services are cost-effective, CMS should uniformly clarify or adopt the policy that "cost-effective" means waiver services will cost no more to the Medicare & Medicaid programs combined than the combined costs of providing Medicare & Medicaid services on a fee-for-service basis to the same population.	Adopted June 2002
190	Give States greater flexibility in developing their programs by stating the purpose of the program (for example, providing health care for low-income individuals) and giving the States the ability to design their own program, in compliance with Federal law, while holding States accountable for achieving the outcomes in accordance with pre-established criteria. (Do not specify how States should meet those criteria.)	Adopted June 2002
210	Issue a Notice of Proposed Rulemaking (NPRM) modifying the regulation at 42 CFR § 488.331, and elsewhere as necessary, to require (as opposed to making optional): • State survey agencies (SAs) and CMS ROs to implement Informal Dispute Resolution (IDR) programs that afford facilities an opportunity to request and receive a face-to-face review for those deficiencies they feel cannot be adequately addressed through telephone or written communication. (NB: Until such time as a regulation can be promulgated, issue instructions encouraging SAs and the CMS ROs to offer face-face opportunities to the maximum extent possible.) • IDRs, as stipulated above, be incorporated as a required step in all provider appeal procedures related to survey and certification (see also recommendation #211), including use of IDR in instances of a surveyor's failure to follow required Federal procedures. • IDRs be conducted in a timely fashion (see also recommendation #218), and notice be given to the facility of its opportunity to request IDR. • That IDR programs be conducted through an independent third party who is not connected to the SA, RO or the facility. Implement the final rule; issue revised instructions and guidance; and provide training to surveyors, States and providers.	Adopted June 2002
211	Issue a NPRM modifying the regulation at 42 CFR § 498 to permit providers the opportunity to (1) appeal noncompliance whether or not a remedy is actually imposed; (2) to challenge severity and scope determinations; and (3) to challenge choice of remedies recommended or imposed, including modification to related citations. Implement the final rule; issue instructional guidance; and provide training to ROs, States and providers.	Adopted June 2002
213 *	Issue a NPRM that would allow CMS to grant waivers to SSAs to test and implement alternatives to the survey and enforcement process currently required to assess Federal quality of care and resident outcome requirements. Implement a final rule, develop criteria and guidance to States in making application to CMS for such waivers; issue guidance for survey and enforcement purposes; provide training to States, surveyors and providers; evaluate the efficacy of waivers that have been granted, in relation to the efficacy of CMS's current survey process in terms of overall improvement to quality and care and resident outcomes.	Adopted June 2002
227	Issue written guidance to surveyors stating that 42 CFR § 418.88b, which requires as a COP for hospice providers that dietary counseling by qualified individuals is available, does not preclude nurses or other qualified health professionals from providing dietary counseling. (Could be implemented with a memorandum.)	Adopted September 2002

#	Adopted Recommendations	Full Committee Action
228	Revise the Hospice COPs to provide an exception to the twenty-four (24) hour nursing services standard in the Hospice COPs when respite care is provided (without undermining basic health and safety standards for hospice patients.)	Adopted September 2002
229	Collaborate with States to ensure that State Plan Amendments and State waiver requests (for example, 1115 waivers) are approved in a manner that is timely, significantly decreases unnecessary documentation, and fosters State program innovation. CMS should adopt a reasonable, workable, preset schedule for completing State requests for plan amendment approvals and waivers. (This would enable States to promptly provide a continuum of services to all beneficiaries in the least restrictive setting, regardless of whether those beneficiaries have disabilities.)	Adopted September 2002 with dissent from Mr. Bloom, Ms. Shafer and Ms. Pattee
231	Recognize the significant impact of COB on the quality of care provided to individuals who are dually eligible to participate in the Medicare & Medicaid programs. Establish an advisory group of key stakeholders including representatives from CMS, fiscal intermediaries, carriers, providers, State Medicaid directors, and beneficiaries to determine a process to significantly improve COB for this group and to reinforce the CMS ROs' authority to deal with regional and other specific concerns that arise. • The advisory group will be established no later than March 31, 2003, and it will have a six-month time frame to submit recommendations.[18] • The advisory group will be charged with finding national solutions to dual-eligible coordination issues including, but not limited to: timeliness of decision making, accountability of FIs, quality assurance, and program issues that impede desired outcomes. The advisory group will focus on formulating best practice guidelines to aid in the decision making process at FI level, creating clear timeframes for decisions on coverage, and assisting with decision-making guidelines. • Recommendations from this advisory group will be relayed to FIs and providers in the form of education about determination of coverage, with the goal of removing obstacles to determination of coverage and quality care.	Adopted September 2002
232	Require that Medicare FIs and carriers pay claims in review for longer than 45 days for unresolved situations in which Medicaid or Medicare may be obligated to pay. Develop systems for Medicare to ensure the timely recoupment of payments that are determined to be the responsibility of Medicaid upon final review.	Adopted September 2002
248	Support government-wide efforts to simplify and harmonize requirements related to human subject research; maintain strong human subject protections and balance individual medical privacy rights with the societal health benefit that results from effective medical research.	Adopted September 2002
249	Support the activities of the HHS Working Group to respond to the National Bioethics Advisory Commission report, *Ethical and Policy Issues in Research Involving Human Participants*.	Adopted September 2002

[18] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation

CHAPTER 5

21ST CENTURY FEDERAL HEALTH CARE PROGRAMS, ELECTRONIC REPORTING, AND PRIVACY

> *"…the UPS (United Parcel Service) person…. has available to him or her a hand held device where all manner of information can be readily accessed in a moment about where packages are, where trucks are, etc. We have nothing analogous to that in the health care system. Instead, we have all these separate data silos that are almost impervious to patients." – Committee Member Bruce Cummings at the January 2002 Meeting, reporting on a discussion of the Data & Information Subcommittee.*

Health care delivery in the United States has changed drastically since the enactment of the Food, Drug and Cosmetic Act in 1938, and then even later with the enactment of the two largest Federal health programs, Medicare and Medicaid, in 1965. Advances in medicine allow many Americans, including senior citizens and individuals with disabilities, to live longer, healthier lives. Advances in technology have resulted in better diagnosis and treatment of a host of diseases and conditions. Patients today receive treatments that were ideas only a decade ago. Advances in information technology have streamlined the transmission of data, reduced storage costs, and added new complexities and new opportunities to enhance care.

While health care innovation has progressed rapidly, the rules that govern Federal health care programs have not kept pace. As a result, both patients and providers feel encumbered by outdated rules or frustrated by their inability to take advantage of current technology. Removing these barriers could improve the effectiveness and efficiency of the programs.

The Committee identified several key ways in which the Department of Health and Human Services (HHS) could better align regulations with the current health care environment, and make HHS programs more receptive to future changes. The use of technology – to improve access to care, to improve quality, and to improve program administration – is discussed below, in addition to suggestions for streamlining the implementation of the Health Insurance Portability and Accountability Act (HIPAA) rules on standardization and privacy.

TECHNOLOGY TO IMPROVE ACCESS TO CARE

Eligibility and enrollment for health programs. Effective application of technology can improve access to care. It can directly improve access to services by providing a vehicle for ensuring that individuals who qualify for government health care programs are identified, notified of their eligibility, and given clear instructions for enrolling in the program. To ensure that individuals receive the full range of services for which they are eligible, it is important that the enrollment process is simple and easy for beneficiaries to use. For example, improved cross-communication among agencies such as the Centers for Medicare & Medicaid Services (CMS), Social Security Administration (SSA), and State Medicaid programs could assist those who are eligible for multiple programs by reducing the number of enrollment or application forms they are required to complete. The Committee recommends that HHS take steps to improve electronic information exchange among the States, CMS, and SSA. The Committee encourages

improvement in the quality of the data exchanged. As part of this effort, HHS should highlight best practices from States that have been most successful in identifying and enrolling individuals who are eligible for more than one Federal program.

Medicare+Choice enrollment. Likewise, the Medicare program provides seniors and individuals with disabilities in many parts of the country the option of receiving their health care through original Medicare or by enrolling in a private Medicare+Choice (M+C) plan. Beneficiaries who opt to enroll in M+C would benefit from application of technology that simplifies the enrollment process. For example, many employers use on-line processes for enrollment and disenrollment in their health plans, and have the capability to permit Medicare beneficiaries to enroll in M+C through those same processes. While the Medicare program works with employers to provide M+C options, enrollees are unable to take advantage of on-line capabilities that are also available through many employer groups. Likewise, other beneficiaries who choose to enroll in M+C plans are unable to enroll using their personal computers because of the requirement for a written signature of a beneficiary's enrollment decision. These M+ C policies limit opportunities that would otherwise make the enrollment and disenrollment process more efficient, less time consuming, and administratively less burdensome for beneficiaries, M+C plans, and employers.

Access to new technologies. Access to effective health care in some cases requires access to the latest advances in technology. One of the obstacles to the acceptance and incorporation of new technology is the fact that scientific advances often occur in bursts – not timed with regulatory or budget cycles – and not always fitting under the purview of one program or one administrative component. For example, an increasing number of new health care products involve a hybrid of pharmaceuticals, biotechnology and medical device technology. Recently, a stent (a device) that is used to hold open a blood vessel closed due to cholesterol plaque was embedded with a drug that would gradually diffuse out to reduce the chance of renarrowing the blood vessel. This new design has the potential to improve health by eliminating the likelihood of recurrent chest pain and need for additional procedures, thereby improving the quality of a beneficiary's life. Yet, products such as the stent that come to the Food and Drug Administration (FDA) for approval face a major process barrier: the FDA has one process to review drugs, and a separate process to review medical devices.

Patients who may benefit from these "combination products" face delays, as the product must be evaluated by two separate parts of the agency. As researchers continue to break down scientific barriers, developing new technologies that no longer fit within the "old" categories, changes are needed to enable the FDA to respond quickly and maintain its focus on safety.

> ***Recommendation:*** **Determine processes for timely review of FDA-regulated combination products by dedicating staff to the development of appropriate policies or establishing of an Office of Combination Products.**

FDA/CMS coverage process. The FDA and CMS have different roles in releasing new technologies to the public. New technology, once approved by the FDA, must then be considered separately for Medicare coverage. Streamlining the process by which CMS decides whether or not to pay for new technologies that are approved by the FDA would enable Medicare beneficiaries to receive important new treatments sooner. Specifically, beneficiaries and medical device manufacturers voiced concerns that even though data collection and other requirements

for FDA approval and CMS coverage are similar, the two approval processes occur along mutually exclusive, sequential timelines. For the most part, the CMS coverage decision process does not begin until after the FDA has approved a new technology.

The Committee urges the Secretary to pursue actions to improve the availability of new medical technologies for Medicare beneficiaries, without sacrificing careful review for safety, efficacy, and improved quality care. Increased cooperation between CMS and FDA could expedite the availability of new technology.

> ***Recommendation:*** **Issue a Memorandum of Understanding (MOU) between the FDA and CMS that considers the interest of stakeholders and defines the process the two agencies will employ to permit the exchange of information and support collaboration relative to their respective review of innovative medical device technologies while maintaining confidentiality of trade secrets and other proprietary data. Propose regulations to achieve specific elements of this recommendation, as needed.**

TECHNOLOGY TO IMPROVE QUALITY

The consistent delivery of high quality care – an outcome valued by patients, providers, and third parties such as employers and health plans – cannot be achieved without innovation in the use of technology. Such innovation will facilitate timely data analysis to inform health care decision-makers at local and national levels. At several regional hearings, the Committee heard from individuals with experience on the front lines of health care delivery, and saw such innovation in action. For example, the Committee learned about the Pittsburgh Regional Healthcare Initiative, a consortium of clinicians, hospitals, health plans, and businesses created with the goal of improving patient safety through the use of existing local information systems and collaboration with HHS's Centers for Disease Control and Prevention. By using a shared regional database and examining local variations in outcomes, on a risk-adjusted basis, this public/private partnership has achieved two of its initial objectives – to reduce hospital-acquired infections and in-hospital medication errors significantly.

The Committee also discussed the value of using an electronic health record to improve health care quality by increasing the accuracy of information and reducing the need for redundant documentation by multiple clinicians. As an example, the Committee learned about the electronic health record developed by the University of Pittsburgh Medical Center (UPMC), when some of its members had an opportunity to witness a demonstration of the UPMC "smart card." These smart cards, which include numerous security features for protecting private health information, are being used by hospital staff to access comprehensive medical history and insurance information, and will provide patients access to their own medical information. The Committee believes that such innovation will increase the accuracy, accessibility, and transferability of important health information. The Committee recognizes that it may be difficult to achieve consensus in the process of building an electronic health record, but that regulators should encourage these efforts.

OASIS/MDS. Post-acute care assessment instruments provide an example of how advances in technology can be harnessed to improve the quality of care. As discussed earlier in Chapter 2,

both the Minimum Data Set (MDS) for nursing facilities and the Outcome and Assessment Information Set (OASIS) for home health agencies (HHAs) are used as tools for patient care planning, internal quality improvement, external oversight, and payment. Nursing homes submit MDS data electronically using software called Resident Assessment Validation Entry Software System (RAVEN); HHAs submit OASIS data electronically using software called Home Assessment Validation Entry Software System (HAVEN). Although both tools are intended for patient populations with similar characteristics and care planning needs, and ultimately, are designed to meet similar objectives, these two tools are not "connected." Thus, a patient discharged from a skilled nursing setting and admitted to a home care setting must be subjected to a full OASIS assessment, requiring potentially unnecessary hassles to, and efforts by both beneficiary and provider. By making the data elements compatible, HHS would create opportunities to streamline information systems. More important, this streamlining would increase the accuracy and reliability of data used for improving quality and patient care planning and would avoid the unnecessary burden of asking beneficiaries the same questions again and again.

TECHNOLOGY TO STREAMLINE PROGRAM ADMINISTRATION

Throughout its deliberations, the Committee noted a number of opportunities to use technology to improve care. There are opportunities to modernize Medicare's administration and operations through the use of new technology not only to streamline operations, but also to improve the ease and flow with which data are transmitted among patients, providers, Federal, State, and local public agencies, private health plans, and others. By using the latest information technology, patients, their families, and the providers who treat them will have more time and resources to engage directly in patient care. Two examples are discussed below.

Electronic signatures. The transition by HHS to allow electronic signatures is currently underway, but in many instances, the requirement for manual signatures remains. For example, CMS requires manual signature and date entry for Medicare cost reports, physicians' orders for durable medical equipment (DME), and provider enrollment applications. Relying on manual signatures is time consuming, demands the retention of hard copy documents, and does not provide any greater degree of security than does the use of electronic signatures. Efforts to offer the option of electronic signatures, while protecting the financial integrity of the program, are strongly encouraged.

Filing of the Medicare Cost Report. The Medicare cost report (MCR) provides another example of an outdated manual document that could be streamlined. While the cost report has evolved from a paper-based form to an electronic format, even in electronic format the MCR must be mailed on a floppy diskette to the Medicare contractor. The Committee notes that HHS could enhance program administration and policy-making by developing the means for electronic filing of the MCR and implementing a way to distribute MCR data immediately, even if unaudited, to public and private stakeholders for better informed decision-making, similar to the Securities and Exchange Commission's EDGAR system.

STANDARDIZATION AND PROTECTING PRIVACY

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 contains provisions that have a significant impact on the administration and operations of the vast majority of health

care providers and health plans, two of which the Committee examined: the standardization of electronically transmitted health care information and the privacy of health care information used by certain "covered entities." The Committee learned about the HIPAA regulations through the testimony of two expert panels, a review of public comments, and the expertise of Committee members. The key issues are discussed below.

Overview of HIPAA electronic transactions. The purpose of HIPAA is to improve the "efficiency and effectiveness of the health care system through the establishment of standards and requirements for the electronic transmission" of health information. (HIPAA Section 261). These standards must "be consistent with the objective of reducing the administrative costs of providing and paying for health care" (the Social Security Act, as amended by HIPAA.) HIPAA requires HHS to issue uniform national standards, including data elements and code sets, for the electronic conduct of the following 10 administrative and financial transactions by health care providers, health care plans, and health care clearinghouses (the "covered entities"):

- Health claims or equivalent encounter information
- Health claims attachments
- Enrollment and disenrollment in a health plan
- Eligibility for a health plan
- Health care payment and remittance advice
- Health plan premium payments
- First report of injury
- Health claims status
- Referral certification and authorization
- Coordination of benefits

The law also requires HHS to adopt unique identifiers and security standards for the transmittal of health information and allows HHS to adopt standards for additional financial and administrative transactions determined to be appropriate by the Secretary.

The Transactions Rule, published on August 17, 2000**,** establishes standards for eight of the 10 transactions listed above. Standards for health claims attachments and first report of injury have yet to be proposed. Once the applicable compliance date occurs, if a covered entity wishes to electronically conduct a transaction for which standards have been set with another entity, the Transactions Rule requires that the entity use only the "standard" transaction. The standard transaction must also be used if a covered entity conducts electronically, within itself, a transaction for which standards have been set.

The Committee heard from many individuals who were concerned that, while the endpoint of administrative simplification is desirable, the process of transition is burdensome. At the May, 2002 regional hearing in Denver, a participant stressed that the regulations need to be released promptly as the health care industry has already committed significant resources to implementing the initial set of administrative simplification rules. The administrative simplification process needs to be more efficient to meet intended goals. To help facilitate implementation of this regulation, the Committee makes this recommendation regarding direct data entry:

> ***Recommendation:*** **Issue clearer rules, including more meaningful compliance guidance, for covered entities regarding conduct of Direct Data Entry (DDE) Transactions (45 CFR § 162.923(b)).**

Specific issues about which the Committee considered recommendations include:

Drug Coding. HIPAA requires that HHS issue uniform national standards, including data elements and code sets, for the electronic transmission of certain administrative and financial health care transactions. Consequently, the Committee recommends the following:

> ***Recommendation:*** **Implement a drug coding system that is standard, updates electronically, and specifically states the product administered.**

Defined schedule for modification to the transactions standards. The Committee recognizes that stakeholders need predictability regarding changes to the transaction standards in order to efficiently and cost-effectively maintain compliant computer transaction capabilities. Changes to transaction standards require computer programming and adequate testing so that changes can be implemented without disrupting health care delivery. Currently, HHS builds no such predictability into the issuance of regulation for transaction standards. For example, the final security, provider identifier, and health plan identifier rules have not been issued, and stakeholders do not know when to expect these rules. The Committee noted that HHS already employs an annual regulatory modification schedule for other regulations – such as Medicare's prospective payment system regulations for hospitals and physicians. A similar approach is recommended for HIPAA regulations, particularly since compliance is so heavily dependent on the interrelationships between various complex rules.

> ***Recommendation:*** **Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the transactions standards, and for compliance with those modifications and additions as follows:**
>
> - **Publish final modifications, additions, and deletions to transactions standards as final rules in the *Federal Register* on the same, pre-set calendar date each year (for example, Dec. 1 or nearest business day before that date.)**
> - **Establish a six-month compliance date for routine modifications and additions to transactions standards.**
> - **Specify a longer compliance period for major transactions standards changes (e.g., replacement of a clinical code set) that require the industry to have very long planning periods.**
> - **Investigate development of a process to identify "minor" modifications and expedite their publication (perhaps via abbreviated rule making) in recognition of the opportunity for public input that is already afforded by the industry standards development process, again based on specified publication and effective dates.**
>
> **[This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in**

others may be far-reaching because of proposals for new transactions, replacing clinical code sets, etc.][19]

Absence of complete transaction definitions. The Committee also noted that the descriptions of a standard transaction may have up to four required elements – a "sender," a "receiver," a "content," and a "purpose." An electronic transmission between covered entities, or within a covered entity, must satisfy each element that applies for that particular transaction to qualify as a standard transaction. For example, the "health care claims" standard transaction must come from a provider (the sender) to a health plan (the receiver) and must contain "a request to obtain payment and the necessary accompanying information" to support the claim (the content) and seek payment for health care (the purpose). In some cases, the regulations are unclear whether a particular transaction must be in standard format. This undermines efficiency, planning, and implementation. Regulated entities should be able to understand their compliance obligations under the Transactions Rule. The Committee recommends:

> ***Recommendation:*** **Require the definition of every standard transaction (45 CFR §§ 162.1101—162.1801) to include a "sender" specification and a "receiver" specification. (For example, revise the "health care claims status" and "referral certification and authorization" standard transactions to add "sender" and "receiver" requirements to their definitions.)**

Definition of "within the same covered entity for electronic transactions." Several providers and plans noted that they did not understand the definition of the phrase "within the same covered entity" as used in the Transactions Rule. In addition, many did not understand the regulation's requirement that they use a standard transaction when the transmission is within the same covered entity. The Committee noted that implementation costs could be reduced by simply deleting the phrase "within the same covered entity" or defining it in a more useful manner. The Committee recommends:

> ***Recommendation:*** **Eliminate or define in a useful manner the meaning of "Within the Same Covered Entity" (45 C.F.R § 162.923(a).) (For example, if the intent of this provision is to require that transactions between health care components doing different covered functions that are part of the same corporate entity ought to be in standard formats, then apply the concepts of "hybrid entity," "covered functions," "multiple-function covered entity," and "health care components" (now applicable only to the HIPAA Privacy Rule) to all of the HIPAA rules, including the Transactions Rule. The "within the same covered entity" provision could then be redefined to apply only to transactions that are between a covered entity's health care components that do different covered functions.)**

Overview of HIPAA Privacy. HHS modified the Privacy Rule by publishing final regulations on August 14, 2002 to address concerns that the Rule could have otherwise inadvertently and

[19] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

adversely affected timely access to quality care.[20] The regulations specify the uses and disclosures that "covered entities" (providers conducting electronic transactions, health plans, and health care clearinghouses) are allowed to make for individually identifiable medical information (referred to as "protected health information.") The regulations give patients new privacy protections, including the right to access their medical records, more control over their health care information – such as prior authorization before covered entities may use or disclose protected information for non-routine uses – and notification of providers' privacy practices.

The Committee heard statements from many providers that the implementation costs are significant without benefiting patients. Providers state that the regulations require them to negotiate privacy agreements with all of their "business associates," which imposes significant legal costs. Similarly, requiring direct treatment providers (e.g., doctors and pharmacists) to give patients a notice of privacy practices by or at first service delivery presents logistical hurdles in some situations, and adds another complex medical form for patients to read and review prior to a service being delivered. Finally, doctors reported being uncertain about the type of information they are allowed to share, and with whom, and noted the risk that enforcement authorities will over-interpret the statute and prevent communication necessary for health care delivery.

The Committee is pleased that HHS has already adopted several provisions that are consistent with Committee recommendations, including:

- The Final Privacy Rule acknowledges that uses or disclosures of patient information that are incidental to an otherwise permitted use or disclosure may occur. For example, as long as they comply with the "minimum necessary" requirements and employ reasonable safeguards, doctor's offices may continue to use waiting room sign-in sheets, hospitals may keep patient charts at bedside, and doctors can talk to patients in semi-private rooms, without fear of violating the rule if overheard by a passerby.

- The Final Privacy Rule gives covered entities (except small health plans) up to an additional year to change existing written contracts to come into compliance with the business associate requirements. The additional time will ease the burden of covered entities renegotiating contracts all at once.

As with many issues, the members of the Committee brought a wide range of personal and professional experiences to the table when they evaluated the privacy issues. There were varied views regarding the requirement to get a patient's written consent before sharing health information. Most Committee members supported eliminating the requirement that patients give written consent before providers could use their health information to provide health care, while others argued that the requirement is necessary for consumers to maintain control of how private information is used.

Specific issues considered by the Committee to be priorities include the following:

[20] The Committee formulated its recommendations regarding the Privacy Rule with public input that was received prior to the issuance of both the March 27, 2002 NPRM and the August 14, 2002 Final Rule, and, hence, descriptions of the public input received and the Committee's recommendations may not reflect those final changes.

Defined schedule for modifications and notice to the privacy standards. Consistent with the need to adopt a defined schedule for issuing modifications to HIPAA's Transactions rules, the Committee noted that HHS should adopt a predictable schedule for amendments to the HIPAA Privacy Rule because a defined cycle would enhance predictability and enable better industry planning, budgeting, implementation, and compliance.

> ***Recommendation:*** **Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the privacy standards, and for compliance with those modifications and additions as follows:**
>
> - **Publish final modifications, additions, and deletions to privacy standards as final rules in the *Federal Register* on the same, pre-set calendar date each year (for example, Dec. 1 or nearest business day before that date.)**
> - **Establish a six-month compliance date for routine modifications and additions to privacy standards.**
> - **Specify a longer compliance period for major privacy standards changes that require the industry to have very long planning periods.**
>
> **[This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in others may be far-reaching.][21]**

Continuous Improvement in the Privacy Rule. The complexity of the Privacy Rule, the broad importance it has on health care delivery, and the need to make continuous improvements in its operation and effectiveness suggest that the public interest and regulatory process would benefit from HHS's continuing receptiveness to public input. The Committee recommends:

> ***Recommendation:*** **Establish a Privacy Rule (PR) advisory panel either within the National Committee on Vital and Health Statistics or as a separate advisory committee or task force, to concentrate on improving the operation and consumer privacy protections of the PR and to advise HHS on the modification, additions, and deletions to the PR's standards and implementation specifications for the defined annual PR Modification cycle. The advisory panel or task force should be comprised of health industry representatives, patients, and health plan enrollees with significant operational experience in the delivery and financing of health care and of representatives from various government agencies, including the Food and Drug Administration, Department of Labor, the Office of the Inspector General, Department of Justice, State Medicaid programs, etc. that regulate activities affecting health care delivery or financing.**

The Committee also heard that certain provisions of the PR and the regulations governing transactions and code sets were inconsistent with current privacy practices, and were unclear or potentially ineffective in achieving their stated goals.

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[21] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

Some additional recommendations on privacy for future consideration by the Department follow:

> ***Recommendation:*** **Require a covered entity that obtains direct or indirect remuneration from a third party for requesting any authorization relating to use or disclosure of an individual's medical information to reveal that fact, as well as the third party source of the remuneration. (This may be achieved by including the following provisions within 45 CFR § 164.508(c)(2):**
> **"(_) If use or disclosure of protected health information by any entity pursuant to an authorization requested by a covered entity will result in direct or indirect remuneration to the requesting covered entity from a third party, a statement that such remuneration will result and identification of the third party or class of third parties who will furnish the remuneration.")**

Regarding business associates:

> ***Recommendation:*** **Modify the PR to specify that a covered entity serving as a business associate must comply with each provision of 45 CFR § 164.504(e)(2) applicable to that business associate relationship. Continue to require that the covered entity specify in writing the uses and disclosures that the business associate covered entity is allowed to make, as required by 45 CFR § 164.504(e)(2)(i).**

Regarding de-identification requirements:

> ***Recommendation:*** **Clarify the de-identification safe harbor knowledge requirement (45 CFR § 164.514(b)(2)) by making clear that "other information" must be available outside the covered entity and by clarifying the meaning of "actual knowledge" in the corporate context. (This may be accomplished by revising 45 CFR § 164.514(b)(2)(ii) as follows:**
> **"(ii) The covered entity determines, after documented inquiry of those of its components that may be reasonably expected to know, that it has no actual knowledge that the information could be used alone or in combination with other information available outside of the covered entity to identify an individual who is a subject of the information.")**

The creative mix of Committee members led to rich discussions about the value of accessing and using new technology to move the Department's programs into the 21st century. Despite varied views, there was consensus within the Committee that a number of issues require further HHS action. There was a difference of opinion on some of the recommendations adopted, privacy being just one example, reflecting differences that have challenged policymakers and society at large.

Master List of SACRR Committee Recommendations [22]
Chapter 5

#	Adopted Recommendations	Full Committee Status
47	Further automate the Minimum Data Set (MDS) process, including the design of publicly available software with "interview wizards" and other intuitive data accumulation methods.	Adopted May 2002
50*	Use the Health Insurance Portability and Accountability Act (HIPAA) mandate as the basis to standardize terminology and identify common data elements used by payers, programs, providers and suppliers of care; and to determine whether the Resident Assessment Protocols (RAPs) are confidential and if any access protections are needed.	Adopted May 2002
51	Develop a standard instrument for the assessment of the health and functional status of patients receiving post acute services as mandated by the Benefit Improvement and Protection Act (BIPA); integrate, to the extent feasible, communication standards adopted under the Consolidated Health Information (CHI) eGov initiative as part of the development of this tool.	Adopted May 2002
60	Consider the impact of HIPAA on home health agencies with respect to the timing of any changes to the Outcome Assessment and Information Set (OASIS).	Adopted May 2002
65	Create modern day electronic and on-line enrollment processes for physicians and Part B suppliers. • Immediately implement a system that allows providers to submit electronic applications via e-mail. • Develop a secure website for provider enrollment.	Adopted May 2002
67	Create and maintain one central repository of forms required or allowed by HHS or its principal components from all of the various HHS websites.	Adopted May 2002
68	Create a continuous review process for all forms with an eye to constantly improving and streamlining existing forms and eliminating obsolete forms.	Adopted May 2002
69	Re-design all forms and data requirements to seamlessly interface with the Information Technology (IT) architecture of HHS so as to minimize human intervention and optimize IT output. Do not publish new forms until IT issues have been addressed.	Adopted May 2002
70	Eliminate Medicare credit balance reporting.	Adopted May 2002
73	Reduce costs and speed up administrative activities for providers, suppliers, health plans, and consumers by modernizing HHS IT, processes, and applications: • Implement use of electronic signatures; • Implement use of e-filing; • Integrate data acquisition into IT architecture of HHS and data providers; • Maximize use of web-based transactions.	Adopted May 2002
74	Modernize current Medicare Cost Report (MCR), make it more useful, more creative, less burdensome. • Eliminate CMS 339; fold data into MCR. • Eliminate need to file redundant manual data to support the MCR. • Modernize and speed up current audit process, settle MCRs within one year and first round appeals within six months. • Establish a method to electronically file MCRs into a central repository similar to the U.S. Securities and Exchange Commission's Electronic Data Gathering and Retrieval (EDGAR) system.	Adopted May 2002
75	Use Generally Accepted Accounting Principles-based cost reporting for providers who no longer receive cost reimbursement; continue to use a simplified and streamlined version of the MCR for cost-based providers.	Adopted May 2002 with dissent from Ms. Pattee.

[22] An asterisk [*] next to the number of a recommendation indicates that legislative action may be required in order for the Department to implement the Committee's recommendation. See Appendix B.

#	Adopted Recommendations	Full Committee Status
77	Connect data instruments and acquisition efforts so data can be transferred and applied to another use or another site of service.	Adopted May 2002
78	Provide resources to meet the January 1, 2005 deadline set by Congress for the development of standard patient assessment instruments as mandated by BIPA. Involve providers and patients in this process.	Adopted May 2002
81	Simplify the authorization process by adopting the Notice of Proposed Rulemaking (NPRM) proposal at (45 CFR § 164.508) that would permit a single, relatively straightforward form to cover all authorization settings.[23]	Adopted May 2002
82	Require a covered entity that obtains direct or indirect remuneration from a third party for requesting any authorization relating to use or disclosure of an individual's medical information to reveal that fact, as well as the third party source of the remuneration. (This may be achieved by including the following provisions within 45 CFR § 164.508(c)(2): "(_) If use or disclosure of protected health information by any entity pursuant to an authorization requested by a covered entity will result in direct or indirect remuneration to the requesting covered entity from a third party, a statement that such remuneration will result and identification of the third party or class of third parties who will furnish the remuneration.")	Adopted May 2002
83	Allow a covered entity to use and disclose the minimum necessary protected health information without individuals' authorizations to distribute a newsletter or similar general circulation communication to a broad cross-section of patients, enrollees or other broad group of individuals . Clarify that this activity is allowed by adding the following new rule as 45 CFR § 164.508(a)(3)(i)(C): "(C) A newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals."	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Ms. Ryan, Mr. Toby
84	Redefine activities that are *not* marketing as follows. As the NPRM proposes, add "care coordination" and "case management" to activities that are *not* marketing, and allow medical information use and disclosure without authorization for communications regarding (a) members of a provider's or health plan's network, (b) products or services, or payments for such products or services, provided by a covered entity or included in health plan benefits, (c) treatment of the individual, or (d) directing or recommending alternative treatments, therapies, health care providers, or care settings. Close loopholes in the NPRM proposal by requiring covered entities to reveal the fact and source of any third party remuneration for making "non-marketing" communications, and allowing individuals to opt out of future such communications. (This may be accomplished by adding the following provisions as new 45 CFR § 164.514(e): "(e)(1) *Standards: certain communications involving remuneration*. Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals, a covered entity that uses or discloses an individual's protected health information to communicate with that individual by any means, other than face-to-face with that individual, about any of the matters described in paragraphs (e)(1)(i)-(iii) of this section, and that receives or will receive direct or indirect remuneration from a third party for making the communication, must meet the requirements of paragraph (e)(2) of this section.	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Mr. Toby

[23] The Committee formulated recommendations 81-98 regarding the Privacy Rule with public input that was received prior to the issuance of both the March 27, 2002 NPRM and the August 14, 2002 Final Rule, and, hence, the Committee's recommendations may not reflect those final changes.

#	Adopted Recommendations	Full Committee Status
	"(i) The covered entity communicates with an individual to describe the entities participating in a health care provider network or a health plan network, or to describe if, and the extent to which, a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits. "(ii) The covered entity communicates with an individual for treatment of that individual. "(iii) The covered entity communicates with an individual for case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual. "(2) *Implementation specifications: requirements relating to certain communications involving remuneration.* Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals or is face-to-face with the individual, a covered entity that makes a communication as described in paragraphs (e)(1)(i)-(iii) of this section and that receives or will receive direct or indirect remuneration from a third party for making the communication must in the communication: "(i) Identify the covered entity as the party making the communication; "(ii) Prominently state that the covered entity has received or will receive remuneration from a third party for making the communication and disclose the name of the third party providing the remuneration; and "(iii) Provide instructions describing how the individual may opt out of receiving future such communications, and for each individual who so opts-out, avoid any future such communications with that individual.") Clarify in the rule, or at least in the preamble to the rule, that an activity that the Privacy Rule characterizes as "not marketing" may still be marketing regulated by other applicable Federal and State laws, such as Food and Drug Administration regulations, CMS rules addressing Medicare+Choice (M+C) materials, and the anti-kickback and anti-influencing laws (Social Security Act §§ 1128A(a)(5), 1128B(b).) HHS Office of Civil Rights (OCR) should coordinate the final "marketing" provisions of the Privacy Rule (PR) with the HHS Office of Inspector General, FDA, and other appropriate Federal agencies to ensure consistency in regulatory provisions among these agencies.	
85	Clarify that incidental use and disclosure is permitted (45 CFR §§ 164.502(a), 164.530(c)) by adopting the NPRM provisions that specify that uses and disclosures reasonably incidental to permitted uses and disclosures of medical information are not violations of the PR.	Adopted May 2002
86	Clarify the provisions on informal permission for persons involved in payment related to an individual's health care, so that communications with family or others acting for an individual "not present" to resolve payment matters relating to the individual's health care, are permitted. (This can be accomplished by rewording of the first sentence of 45 CFR § 164.510(b)(3) as follows: "(3) *Limited uses and disclosures when the individual is not present*. If the	Adopted May 2002

#	Adopted Recommendations	Full Committee Status
	individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care or payment related to the individual's health care.")	
87	Reconcile potential conflict between confidential communications and explanations of benefits (EOB) issuance (45 CFR §§ 164.501 ("Payment"), 164.522(b)(1)) by clarifying that a health plan may require the person demanding confidential communication to explain how the health plan can perform its payment obligations of issuing EOBs to the subscriber. Require the HHS OCR to coordinate the PR with the rules of the Department of Labor's (DOLs) Pension and Welfare Benefits Administration, which regulates Employee Retirement Income Security Act (ERISA) group health plans, in order to avoid conflicting compliance obligations for ERISA group health plans and the health insurers that administer or underwrite them. [This may be accomplished by rewording 45 CFR § 164.522(b)(2)(ii)(A) to State, "When appropriate, information as to how payment activities, including issuance of explanations of benefits to the insured under a health plan, will be handled." Another potential solution is to allow a health plan to warn in its notice of privacy practices that requests for confidential communications may not prevent the insured under a health plan from receiving other information, such as explanations of benefits for others covered by the insured's policy or benefits plan, that may alert the insured that the individual requesting confidential communications obtained health care. Yet another is to permit a health plan to inform an individual requesting confidential communication that the individual may have to pay for the care to avoid the health plan providing information to the insured through other explanations of benefits or similar communications that may alert the insured that the individual obtained health care in confidence.]	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Ms. Ryan
88	Delete the endangerment requirement at 45 CFR §§ 164.524(a)(3), (4), (d)(2) and leave it to the health care professional's judgment, exercised in the best interest of the individual or others, whether requested protected health information should be made available to an individual or the individual's personal representative. Continue to grant the individual or the individual's personal representative denied access, based on that exercise of professional judgment, the right to have another professional review the access denial. Allow the explanation for the denial to be, simply, "Information has been withheld based on the judgment of a qualified health care professional." [The revised rule and procedures would thus state: "§ 164.524(a) . . . "(3) *Reviewable grounds for denial*. A covered entity may deny an individual or an individual's personal representative access to specific protected health information concerning the individual if a licensed health care professional has determined, in the exercise of professional judgment, that providing access to that protected health information is not in the best interest of the individual or others. The individual or the individual's personal representative has the right to have such denial reviewed in accordance with the procedures of paragraph (d)(4) of this section. "[Delete paragraphs (a)(3)(i)-(iii) and (a)(4) of this section.]	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Ms. Ryan and Mr. Toby

#	Adopted Recommendations	Full Committee Status
	"(b) *Implementation specifications: requests for access and timely action.* . . . "(2) *Timely action by the covered entity*. (i) . . . the covered entity must act on a request for access no later than 30 days after receipt of the request as follows. . . . "(B) if the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section. . . . "(d) *Implementation specifications: Denial of access*. If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements. . . . "(2) *Denial*. The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain: "(i) The basis for the denial. If the denial of access is in accordance with paragraph (a)(3) of this section, it is sufficient to state, "Information has been withheld based on the judgment of a qualified health care professional." "(ii) If the denial is in accordance with paragraph (a)(3) of this section, a statement of the individual's review rights under paragraph (d)(4) of this section, including a description of how the individual may exercise such review rights. "(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii) "(4) *Review of denial requested*. If the individual or the individual's personal representative requests review of a denial of access under paragraph (a)(3) of this section, the covered entity must designate a licensed health care professional to review the decision to deny access. This designated reviewing official must not have been directly involved in the denial, and must be qualified by training or experience to make an informed evaluation whether withholding the protected health information to which access has been denied is in the best interest of the individual or others. The covered entity must promptly refer the request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable time, whether to deny or grant the access requested based on the designated reviewing official's professional judgment, exercised in the best interest of the individual or others. The covered entity must promptly provide written notice to the individual or the individual's personal representative of the determination of the designated reviewing official, and take all action required by this section to carry out the designated reviewing official's determination."]	
89	Allow an additional year for covered entities to conform pre-existing contracts with business associates to the PR's requirements, and issue the model business associate terms suggested by the NPRM.	Adopted May 2002
90	Modify the PR to specify that a covered entity serving as a business associate must comply with each provision of 45 CFR § 164.504(e)(2) applicable to that business associate relationship. Continue to require that the covered entity specify in writing the uses and disclosures that the business associate covered entity is allowed to make, as required by 45 CFR § 164.504(e)(2)(i). [This provision is needed because a business associate is permitted to use and disclose the protected health information of the covered entity it serves only as that covered	Adopted May 2002

#	Adopted Recommendations	Full Committee Status
	entity allows. This approach can be implemented as follows. Revise 45 CFR § 164.502(e)(1)(iii) to state: "(iii) A covered entity acting as the business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e) of this subpart if the business associate covered entity violates any of the provisions of § 164.504(e)(2) of this subpart, including any use or disclosure of the protected health information of the covered entity on whose behalf the covered entity business associate is acting that is inconsistent with the uses and disclosures of such information specified in writing as required by paragraph (e)(2)(i) of this section by the covered entity on whose behalf the business associate covered entity is acting." Revise 45 CFR § 164.502(e)(2) to state: "(2) *Implementation specification: satisfactory assurance*. A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section by: "(i) For a business associate who is also a covered entity, specifying in writing the permitted and required uses and disclosures of the covered entity's protected health information by the business associate in compliance with § 164.504(e)(2)(i) of this subpart. "(ii) For a business associate who is not a covered entity, obtaining a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e) of this subpart."]	
91	Adopt the NPRM proposal at (45 CFR §§ 160.202, 164.502(g)) to clarify that parents' access to the medical information of their unemancipated children is controlled by State law, and when State law is silent, by the covered entity's professional judgment.	Adopted May 2002
92	Adopt the NPRM proposal at (45 CFR § 164.504(a)) to remove "primary" from the hybrid entity definition and give any covered entity with non-covered functions the option to designate itself a hybrid entity. [By adopting this proposal, the covered entity will be required to identify each of its operations that perform covered functions and subject these health care components, as well as each component that serves the health care components in a business associate capacity, to Privacy Rule compliance. The effect will be that the health care components, and the components serving them in a business associate capacity, may not disclose their protected health information to, or allow their protected health information to be used by, non-health care components unless the Privacy Rule allows such disclosure or use. For example, a health care component will not be allowed to disclose its protected health information to the covered entity's human resources personnel performing non-covered employment functions. It also means that individually identifiable health information held by the covered entity's non-health care components (*e.g.*, health information in the human resources department is not protected health information subject to the PR.)]	Adopted May 2002
93	Adopt the NPRM proposal at [45 CFR § 164.501 ("Protected Health Information")] that would exclude employment records from the protected health information definition.	Adopted May 2002
94	Adopt the NPRM proposal at (45 CFR § 164.504(f)) to explicitly state that a health plan may disclose enrollment data to the employer or other sponsor of the group health plan, even if the sponsor does not qualify under the PR to perform plan administration functions.	Adopted May 2002
95	Adopt the NPRM proposal at (45 CFR § 164.514(b)(2)(i)(R)) that would make clear that a re-identification code or key under (45 CFR § 164.514(c)) does not have to be	Adopted May 2002

#	Adopted Recommendations	Full Committee Status
	deleted to de-identify data.	
96	Clarify the de-identification safe harbor knowledge requirement (45 CFR § 164.514(b)(2)) by making clear that "other information" must be available outside the covered entity and by clarifying the meaning of "actual knowledge" in the corporate context. (This may be accomplished by revising 45 CFR § 164.514(b)(2)(ii) as follows: "(ii) The covered entity determines, after documented inquiry of those of its components that may be reasonably expected to know, that it has no actual knowledge that the information could be used alone or in combination with other information available outside of the covered entity to identify an individual who is a subject of the information.")	Adopted May 2002
97	Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the privacy standards, and for compliance with those modifications and additions as follow: • Publish final modifications, additions, and deletions to privacy standards as final rules in the *Federal Register* on the same, pre-set calendar date each year (for example, Dec. 1 or nearest business day before that date.) • Establish a six -month compliance date for routine modifications and additions to privacy standards. • Specify a longer compliance period for major privacy standards changes that require the industry to have very long planning periods. [This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in others may be far-reaching.][24]	Adopted May 2002
98	Establish a PR advisory panel either within the National Committee on Vital and Health Statistics or as a separate advisory committee or task force, to concentrate on improving the operation and consumer privacy protections of the PR and to advise HHS on the modification, additions, and deletions to the PR's standards and implementation specifications for the defined annual PR Modification cycle. The advisory panel or task force should be comprised of health industry representatives, patients, and health plan enrollees with significant operational experience in the delivery and financing of health care and representative of various government agencies, including FDA, DOL, OIG, Department of Justice, State Medicaid programs, etc. that regulate activities affecting health care delivery or financing.	Adopted May 2002
103	Expand the J Code system to more accurately define the package size used. If available package sizes are 100 mg, 200 mg, and 1 gram, have separate codes for each of those sizes, with corresponding reimbursements.	Adopted June 2002
104	Further clarify the HIPAA final transaction rules to allow providers to make changes in the event the National Drug Codes (NDC) system is going to remain a part of the initial HIPAA transactions codes implementation.	Adopted June 2002
105	Clearly define covered drug products instead of broadly defining what may qualify as self-administered.	Adopted June 2002
106	Use patient-specific modifiers that may move drugs into a covered category for patients with limited mobility and/or capability to understand therapeutic schedules.	Adopted June 2002
107	Implement a drug coding system that is standard, updates electronically, and specifically states the product administered. (Currently the only such coding system that exists is the NDC coding system.)	Adopted June 2002

[24] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

#	Adopted Recommendations	Full Committee Status
125	Explore the feasibility of permitting members of employer group health plans or individuals who have access to a personal computer to enroll and disenroll electronically from M+C plans, and begin a pilot to test said procedures, respecting security, privacy and other related matters.	Adopted June 2002
185	Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the transactions standards, and for compliance with those modifications and additions as follow: • Publish final modifications, additions, and deletions to transactions standards as final rules in the *Federal Register* on the same pre-set calendar date each year (for example, Dec. 1 or nearest business day before that date.) • Establish a six- month compliance date for routine modifications and additions to transactions standards. • Specify a longer compliance period for major transactions standards changes (e.g., replacement of a clinical code set) that require the industry to have very long planning periods. • Investigate development of a process to identify "minor" modifications and expedite their publication (perhaps via abbreviated rule making) in recognition of the opportunity for public input that is already afforded by the industry standards development process, again based on specified publication and effective dates. [This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in others may be far-reaching because of proposals for new transactions, replacing clinical code sets, etc.][25]	Adopted June 2002
186	Require the definition of every standard transaction (45 CFR §§ 162.1101 162.1801) to include a "sender" specification and a "receiver" specification. (For example, revise the "health care claims status" and "referral certification and authorization" standard transactions to add "sender" and "receiver" requirements to their definitions.)	Adopted June 2002
187	Eliminate or define in a useful manner the meaning of "Within the Same Covered Entity" (45 C.F.R § 162.923(a)). [For example, if the intent of this provision is to require that transactions between health care components doing different covered functions that are part of the same corporate entity ought to be in standard formats, then apply the concepts of "hybrid entity," "covered functions," "multiple-function covered entity," and "health care components" (now applicable only to the HIPAA PR) to all of the HIPAA rules, including the Transactions Rule. The "within the same covered entity" provision could then be redefined to apply only to transactions that are between a covered entity's health care components that do different covered functions.]	Adopted June 2002
188	Issue clearer rules, including more meaningful compliance guidance, for covered entities regarding conduct of Direct Data Entry (DDE) Transactions (45 CFR § 162.923(b)).	Adopted June 2002
203	Revise the Medicare & Medicaid cost reports to reflect the current purpose and use of these two separate documents. The data should be sufficient to create, as required by Congress, a Skilled Nursing Facility (SNF) wage index, appropriate market basket update and other purposes that CMS can justify.	Adopted June 2002
215	Modify existing regulations in order to allow providers the option to utilize electronic images, transmittals and automated vendor file exchange data receipts as evidence to support costs claimed for reimbursement in place of the currently required "hard copy" originals of such evidence.	Adopted June 2002
222	Create a FDA/HHS Working Group of all affected stakeholders to look at the current	Adopted June

[25] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

#	Adopted Recommendations	Full Committee Status
	IT systems that have automatic reporting for adverse events, adverse drug reactions and medical errors; study the feasibility of developing a National Automatic System. (An existing example can be found on the web at www.PRHI.org.)	2002
224	Design and implement, as soon as possible, a demonstration project to deploy Medicare smart cards to selected beneficiaries. Include a chip on the card that would contain basic beneficiary data in a write-protected form so it could not be altered by an unauthorized user. Ensure that the smart card can be used by providers, beneficiaries, and the industry to store information. (Note: the long-term goal of this initiative is to create an electronic medical record.)[26]	Adopted September 2002
225	Establish a multidisciplinary panel to evaluate open architecture applications for use with a Medicare smart card. Direct the panel to make recommendations to approve or reject proposed open architecture applications for the Medicare smart card. Give special attention to privacy concerns. Seek technical assistance from the OIG to prevent fraud and abuse. ("Open architecture" provides a platform on which users can layer software and data. Outside groups would be encouraged to develop ways to expand the card's use beyond simple identification with data stores and interfacing applications. Additional issues for consideration upon deployment of a smart card include: • determining whether all applications developed by the health care community should be funneled to the panel for consideration before being implemented or whether this panel would support a community model in which various entities would develop software applications themselves on an ongoing basis, producing creative mechanisms and seeking industry-wide standards, • acknowledging that the technological capacity of smart cards may require some organization to set parameters on the use of the card and the types of software that would be permitted for inclusion on the card, and • developing a formal public/private partnership to support private sector innovation for a government sponsored product and reconcile any issues that arise from this partnership.[27]	Adopted September 2002
226 *	Use the Medicare smart card as a tool for integrating medical information across the continuum of care over the long term. For example, allow for the integration of data from future electronic standard assessment instruments, enrollment forms, and medication administration records into smart card technology.	Adopted September 2002
233	Develop an online, real-time claims adjudication system for Medicare that gives payors information relating to coverage, reimbursement and coordination of benefits at the point of service whenever possible.	Adopted September 2002
236*	Issue a Memorandum of Understanding (MOU) between the FDA and CMS that considers the interest of stakeholders and defines the process the two agencies will employ to permit the exchange of information and support collaboration relative to their respective reviews of innovative medical device technologies while maintaining the confidentiality of trade secrets and other proprietary data. Propose regulations to achieve specific elements of this recommendation, as needed.	Adopted September 2002
237	Formally promote and encourage the implementation of processes to expedite FDA notification of CMS when an Investigational Device Exemption (IDE) designation, i.e., Category A or B, has been granted, and ensure complete and timely CMS transmittal of such notification to local carriers and fiscal intermediaries.	Adopted September 2002
241*	Establish a process, with input from affected stakeholders, to enable early coordination between FDA and CMS and, when appropriate, permit parallel reviews, during the	Adopted September 2002

[26] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

[27] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

#	Adopted Recommendations	Full Committee Status
	design of clinical trials for medical device technologies thereby promoting more timely patient access to innovative therapies without slowing down the FDA approval process.	
242*	Announce publicly and promote through outreach to stakeholders the process (e.g., relevant structures and time frames) for the implementation of recommendations relating to FDA/CMS coordination related to new medical device technologies.	Adopted September 2002
243	To facilitate timely release of new medical device technologies and to enable CMS to support the processes for enhanced FDA/CMS coordination on new medical device technology issues: • Encourage CMS to issue guidance in consultation with stakeholders on Medicare coverage standards (guidance is not legally binding); • Recognize the importance of and support the maintenance of local medical review policies (LMRPs); • Support the timely issuance of Health Common Procedure Coding System (HCPCS) consistent with the Advisory Committee's recommendation to adopt a defined schedule for issuance of proposed and final modifications, additions and deletions to the transaction standards; (see recommendation 185) • Eliminate the requirement to submit six months of marketing data (post-FDA approval) prior to the acceptance of the HCPCS application; • Improve the effectiveness and efficiency of the national coverage decision process by promoting CMS consideration of reliable data from outside sources in the coverage and payment review processes; • For decisions involving national coverage for new technologies without a referral for technology assessment or to the Medicare Coverage Advisory Committee (MCAC), direct CMS to establish and maintain a six-month time frame for issuing decisions. If a referral is required, establish and maintain a 12-month timeframe for decisions; • Allocate adequate CMS staff and resources to meet expedited time frames for national coverage decisions.	Adopted September 2002 with dissent from Ms. Ryan and Mr. Bloom
244	Determine processes for timely review of FDA-regulated combination products by dedicating staff to the development of appropriate policies or establishing a new Office of Combination Products.	Adopted September 2002

LONG TERM VISION

The Department of Health and Human Services (HHS) includes the Centers for Medicare & Medicaid Services (CMS), and the Food and Drug Administration (FDA), among other important agencies. Over time the programs and regulatory responsibilities with which these agencies are tasked have become quite complex, with the following results: regulations governing Medicare & Medicaid can often interfere with the process of delivering care to the programs' beneficiaries, adversely affect physicians and providers who render that care, and in some situations, prevent beneficiaries from receiving the services to which they are entitled. Similarly, while the FDA has made progress during recent years in streamlining operations and improving customer service, the Committee heard that improvements are still needed to ensure that drugs, biologics, and devices are safe and that consumers and patients have access to medical innovation that can improve or extend their quality of life. Much can be done to improve health care services and products for all Americans and make the functioning of HHS regulations and programs work better for the individuals and organizations who are responsible for the delivery of health services or the development of regulated products.

Though most of the short-term recommendations from the Committee relate to Medicare, more of the long-term recommendations are applicable to the regulatory processes used by both agencies. The Committee offers these recommendations for improvement in the regulatory process so that it is not necessary to convene a committee of this kind again in the future. Some of these suggestions could be accomplished within the management structure and regulatory process of HHS; others would require legislative changes, management structure changes or resource allocation decisions. But a vision is needed to guide the process of making the needed improvements in the regulatory process to solve the fundamental problems that exist today. This chapter outlines the Committee's vision of the future and then offers thoughts about how to achieve the vision.

PROBLEMS WITH THE CURRENT SYSTEM

The current regulatory process expends considerable energy and effort on annual updates of payment systems for inpatient hospital care, outpatient hospital care, physician services, ambulance services, nursing home care and more. These routine updates alone require considerable effort. The work of crafting new regulations in response to Congressional action provides a major challenge to HHS. Adequate human resources and technology investments will be needed to achieve a higher level of service to beneficiaries and providers. The problem must be remedied before truly effective long-term improvements in service can be achieved. For example, it will not be possible to provide a pre-authorization system for Medicare beneficiaries that would enhance service to beneficiaries and remove the uncertainties of the current system without additional resources.

The current regulatory process diverts precious resources from direct patient care or service. Some of the financial and human resources needed to achieve service improvements and overall performance can come from elimination of regulatory processes that do not add value for

beneficiaries. The savings generated from regulatory simplification and restructuring could be used for other important programs and services.

Today's system of health care regulation is in need of redesign in order to build a high quality health care system for the 21st Century. The time has come for all stakeholders in the health care system to begin a process of redesigning the regulatory system to improve its effectiveness and address system-wide problems. Achievement of the Committee's vision requires a quality design effort that spans several years, and potentially, new funding sources. The approach should be based on the following general guidelines and principles, some of which are not new, but perhaps have been forgotten or need to be re-emphasized:

GUIDING PRINCIPLES

- Regulations should be uniform and streamlined to avoid conflict and duplication.

- Regulations should have a clearly articulated purpose that advances an appropriate regulatory function.

- Regulations should be written clearly to promote easy understanding by consumers, employers and health care providers, suppliers and organizations.

- Regulations should be based on evidence from research and peer-reviewed literature, wherever possible, not on anecdotes or interest group politics.

- Regulations should be based on the premise that value is added for consumers (i.e., better service, access, and affordability) and providers or other entities (i.e., improved ability to serve patients without excessive operational costs to comply with regulatory requirements.) Regulations that do not meet such a cost-benefit analysis should not be adopted.

- Regulations should avoid micromanaging the process by which entities operate and instead should focus broadly on improving performance in the areas of quality, solvency, accessibility and affordability.

- Regulations should assure consumers that providers, suppliers and health care organizations will be held accountable for providing the benefits, services and products they promise and, where appropriate, for achieving targets for improved performance. By the same token, they should be given greater flexibility to achieve those goals.

A specific framework for the future structure of regulatory process would incorporate the following elements:

- Redirection of resources: short-term savings from regulatory streamlining efforts should be used to expand the resources devoted to patient care.
  - savings that could afford greater access to care for the uninsured
  - savings that could provide for even greater flexibility in delivery of care.

- A public-private initiative to establish quality standards.
  - standards that strengthen the safety of services
  - standards that reduce unnecessary or duplicative services

- A significant role for technology.
  - technology products that improve the delivery of direct health care and speed administrative functions
  - information technology that facilitates the achievement of quality, access and fiscally prudent standards

- A new emphasis on changes in statutory basis for reimbursement within existing expenditure constraints:
  - a system that rewards quality outcomes, not processes
  - a system that balances the need for acute care services with the growing need for services provided to the chronically-ill and those requiring long-term care
  - a system that acknowledges the fact that outcomes may only mean maintenance of and not improvements in health status, and support for dignified death.

- A more global system of payment within government programs that gives providers more flexibility, and patients more choices and greater ability to be prudent users of public resources.

The regulatory process needs to operate in an integrated fashion; too often the regulatory process is fragmented. Regulations in one area may conflict with the regulatory requirements in another. Unnecessary duplication of effort also occurs in regulation and program administration. For example, a Medicare beneficiary may have separate data collected from hospitals for Part A care, physicians for Part B, home health (OASIS), a nursing home (MDS), and durable medical equipment—much of it having no clinical relevance. Thus, there are multiple regulatory requirements for data collection, creating a multiple data sets for the same beneficiary and no ability to integrate across programs, databases, or processes of care to make care better. A different approach should be taken. There should be a patient-centered record, supported by improved information technology using smart card and other technological capabilities. Information technology advances should permit data to be collected for clinical purposes, and used for payment and quality purposes without overlaying expensive, confusing, and burdensome separate reporting systems.

HHS should improve communication between programs and achieve true integration to serve beneficiaries and providers, building on the success of the Medicaid waiver process. Important program improvements that are successfully studied and implemented in the context of Medicaid demonstration programs should be evaluated for rapid incorporation into Medicare programs. These changes will require Congressional action.

An orientation to service requires that new measures of performance be incorporated in program management and assessment of effectiveness. For example, service should be measured by the frequency with which beneficiaries are enrolled without problems, or how many providers are registered within 21 days, or how often the right answer is provided to callers to help lines.

Rather than concentrating on completion of forms to collect data that are not directly related to patient care, the emphasis should be on the quality of clinical performance. Regulations run the risk of creating barriers to innovation by forcing all providers to work backward to a basic level of functioning. There is already work underway in CMS to improve the ability to care for patients with certain diseases and conditions, and these efforts could be helped by redirection of resources from regulatory processes that do not add value to these important quality-oriented practices.

An assessment of the value of simplification should include operational savings from simplified processes that avoid duplication of effort and are more likely to result in the desired improvements in service and quality of care. The Committee (and others) has tried to estimate the potential savings, but an accurate assessment of potential savings will require additional work by the Department. [28]

Regulation in the health care field has grown by a steady process of accretion. It has resulted in a system that is duplicative, intrusive, and too often in conflict with itself. Indicative of the problem, no one knows the cost of these regulations. This should be determined, or at least estimated. While each new regulatory scheme appears on its face, and at first, to be beneficial, it is critical to know whether the benefit is real, particularly as it evolves over time, as circumstances change, and as patients and providers deal with the cumulative effect of these regulations.

The experience of Medicare demonstrates the need to consider new approaches. As outlined elsewhere in this report, regulations are frequently invasive and prescriptive. Too often regulations stand in the way of patients being able to get the care they need and that their providers are ready to provide. The regulations have grown over time, each one addressing a perceived problem, followed by ambiguous interpretations, bulletins and even more regulations to make the initial ones "work." The Committee has outlined a number of recommendations to change the regulations, and this statement of long-term recommendations is intended to prevent the problems identified through this effort from occurring again. However, it may well be that no matter how skilled and well-meaning the government officials, and no matter how the process is improved, the effort to regulate on a service-by-service basis every element of the provision of care to Medicare beneficiaries inevitably results in the kinds of regulatory problems the Committee has identified. The effort to control, by statute and regulations, the vast variety of circumstances that are presented, and the complexity of health care itself, will inevitably lead to regulatory problems.

Sometimes it is necessary to consider bold changes rather than small, incremental problem-oriented fixes. The system should be patient-centric. A system centered on the patient (and on the consumer before she or he becomes a patient) will reduce the need for intrusive, detailed regulation. Given more power to make their own decisions and more control over the use of their resources for care, patients, with good information, can use their purchasing power (and intermediaries working on their behalf) to mitigate the need for complex and detailed regulation.

[28] Others, including the American Hospital Association and Blue Cross Blue Shield Association, have attempted to estimate the burden on various sectors.

APPENDICES

APPENDIX A

COMMITTEE ORGANIZATION

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COMMITTEE ORGANIZATION

As an independent, objective body, the Committee had broad latitude in developing its structure. The Committee considered organizing by stakeholder group or forming workgroups to address discrete problems. The Committee determined that subcommittees examining cross-cutting themes would have the advantage of utilizing the broad representation of viewpoints and backgrounds of committee members on each subcommittee. Therefore, the Committee organized around four broad themes that emerged from initial stakeholder listening sessions. Subcommittees were asked to identify priority topic areas within each of the four themes and to draft recommendations for consideration by the full Committee.

The **Data & Information Subcommittee** focused on the potential for streamlining, reducing or eliminating unnecessary data collection and reporting requirements. The subcommittee also addressed improving the manner in which data and information are transmitted between and among public and private stakeholders.

The **Flexibility in Regulations Subcommittee** explored how regulations and the regulatory process can respond to rapidly evolving operations, delivery, and product changes in the health care market. The subcommittee considered improvements in the regulation implementation process and guidance through evidence-based rulemaking, uniform application, and evaluation and feedback mechanisms. Further, the subcommittee sought to improve the process for identifying and removing obsolete regulations and the systems that support them.

The **Communications and Oversight Subcommittee** analyzed the clarity of communications for all intended audiences with particular emphasis on beneficiaries and providers, moving regulatory oversight from an adversarial model to a more collegial model, and improving the accuracy of information for providers and beneficiaries.

The **Coordination Subcommittee** examined the key intersections in the health care system, i.e., where State regulations meet Federal regulations, or one site of care intersects another. For example, the subcommittee discussed obstacles faced by beneficiaries dually eligible for Medicaid (a Federal-State program) and Medicare (a Federal program) as well as obstacles faced by providers attempting to coordinate current privacy practices with new Federal rules driven by the Health Insurance Portability and Accountability Act. The Subcommittee also considered the burden experienced by many stakeholders arising from duplication or conflicts within rules imposed by Federal and State agencies, accrediting organizations as well as other organizations. Under the Coordination Subcommittee's auspices, the Committee convened an ***ad hoc* committee** to analyze **FDA** regulatory reform options pertaining to drugs, devices and biologics.

Public Input

The Committee collected suggestions and advice from the public in several ways.

Regional Hearings. The Committee conducted a series of hearings to take testimony on how Departmental rules and regulations affect communities on the local level. The Committee held several meetings in Washington, DC, including a public teleconference, and also visited Miami, FL; Phoenix, AZ; Pittsburgh, PA; Denver, CO; and Minneapolis, MN. The primary components of each of the five regional hearings included:

- *Testimony on Selected Topics*. A series of topics were selected based upon priorities the Committee adopted at its first meeting. Panels of invited speakers with focused expertise or experience made formal presentations to the Committee.

- *Public Comment.* Time was scheduled at each regional hearing for members of the general public to address the Committee. The Committee heard from all individuals in attendance who wished to speak on suggested improvements and general areas of concern.

- *Site Visits.* In conjunction with each hearing, Committee members took the opportunity to visit local health care facilities or operations. These visits provided individuals served by or working in those sites the chance to speak one-on-one with Committee members.

Written Comments. The Committee also issued a formal solicitation for written input in the *Federal Register*. Six hundred and twelve (612) comments were received via internet and mail. Comments submitted electronically were entered into a searchable database, viewable on the HHS regulatory reform website. Sub-committees reviewed all public comments in the topic areas under their consideration.

Transcripts. The full text transcript for all SACRR meetings, including the final meeting on November 21, 2002, is available at http://www.regreform.hhs.gov.

MAJOR ISSUES RAISED IN PUBLIC COMMENT

Advance Beneficiary Notices
Audits, Surveys, Fraud & Abuse Enforcement
Certificates of Medical Necessity
Clinical Laboratory Improvement Amendments (CLIA)
CMS/FDA Coordination – New Technology
Communication for Beneficiaries
Conflicting Regional Office Policies and Rules
Coverage / Reimbursement / Payment Rate Issues
Diagnosis Information on Laboratory Forms
E&M Documentation Guidelines
EMTALA
FDA – Adverse Drug Reporting
FDA – Health and Biomedical Research
FDA – Other
FDA – Pre- and Post-Market Review of Pharmaceuticals and other Products
HIPAA Administrative Simplification
HIPAA Privacy
Homebound Definition for Home Health

Lack of Needed Regulations
Limited English Proficiency Issues
Local Medical Review Policies
Medicaid – Other
Medicaid Managed Care Quality and Reporting Requirements
Medicare Claims Appeal Process
Medicare Conditions of Participation
Medicare Cost Reports, Hospitals
Medicare Cost Reports, Nursing Facilities
Medicare Provider Enrollment (Form 855)
Medicare Secondary Payer Form
Medicare/Medicaid Dual Eligibles
Medicare+Choice Issues
Minimum Data Set (MDS)
Multiple Reviews
Nursing Home Inspection & Regulation
Other Provider-Specific – Home Health Agencies
Other Provider-Specific – Hospitals
Other Provider-Specific – Nursing Facilities
Other Provider-Specific – Physicians
Outcome and Assessment Information Set (OASIS)
Problems with Fiscal Intermediaries and Carriers
Process for Removing Obsolete Rules
Regulation Development Process / Presentation of Regulations
Rural Issues
Seclusion and Restraint Regulations
State / Federal Coordination

STAKEHOLDER GROUPS WHO SUBMITTED PUBLIC COMMENTS

Consumer Advocate
Drug Company
Employer
Home Health Agency
Hospice
Hospital
Insurance Company
Laboratory
Medical Device Maker
Medical School/Researcher
Nurse
Nursing Facility
Patient
Pharmacist
Physician
Regulator/Government Agency
Other

APPENDIX B

THE MASTER LIST OF ADOPTED RECOMMENDATIONS

APPENDIX B
THE MASTER LIST OF ADOPTED RECOMMENDATIONS

The Secretary's charge to the Committee was to restore common sense to the regulatory process so that Americans can receive high quality care easily and without having to overcome regulatory hurdles. Secretary Thompson asked the Committee to focus on areas where real changes can be made that improve the quality of care. Although regulations governing Medicare, Medicaid and the Food and Drug Administration were to be the primary focus, the Secretary, in his desire to make regulations more effective and efficient, also asked that the Committee identify specific provisions that may lead to unnecessary and excessive regulatory burden and that Congress may need to address. The Committee has not considered possible budgetary impacts. It may be that when a careful budget analysis is complete it could have an effect on a recommendation's feasibility. [Those marked by an asterisk [*] may require legislative action.]

No.	Adopted Recommendation	Committee Action
1	Publish a final rule on the previously proposed rule on Conditions of Participation (COPs) for home health agencies (HHA) currently in the queue.	Adopted May 2002
2	Announce removal of the Proposed Rules on HHA CPOs from the docket if the proposed rule remains dormant for more than six months from the date of adopting this recommendation. [29]	Adopted May 2002
3	Eliminate or modify the definitions of branch office and sub-unit contained within Medicare's COPs for HHAs to reflect current technology and accepted practices.	Adopted May 2002
4	Allow Medicare + Choice Organizations (M+Cos) to access State and county codes, and input changes to that data element during the summer of 2002 for payment reconciliation of special status Medicare enrollees. (Direct access to proprietary information held in Federal databases would be limited in accordance with the Privacy Act.) [30]	Adopted May 2002
5	Determine new procedures for processing working aged enrollments for M+CO payment reconciliation purposes and establish pilot. Analyze systems issues with ESRD	Adopted May 2002

[29] The date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[30] The date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendation	Committee Action
	enrollments and propose workarounds.	
6 *	Simplify the Medicare program's data filing process requirements in Adjusted Community Rate Proposals (ACRs) for M+C health plans; prepare a report due September 30, 2002 to inform that goal which examines the following options: • Statutory recommendations that would allow plans to use M+C only data in doing their ACRs; • Allow M+COs to make greater use of actuarially-generated information rather than information from the accounting systems in the ACR; • Reduce the number of filings for the 2004 filing; • Reduce the back-up documentation required for the 2004 filing; • Use simpler filing forms similar to those used in State Department of Insurance filings; and • Reduce the number of benefit categories submitted in the ACR for the 2004 filings.[31]	Adopted May 2002
7	Provide additional comprehensive training for auditors concerning the development of ACR proposals in order to decrease the occurrence of erroneous and incorrect findings; include industry experts in the faculty for the training sessions. Consult with industry experts in the design of the training.	Adopted May 2002
8	Convene a work group whose goal is to pursue alternative methods of determining a M+COs compliance with Medicare's regulations, such as by data-driven and "focused review"-based biennial monitoring visits. (Plans with good performance should not be subject to total review.) Implement work group's recommendations no later than January 1, 2004.[32]	Adopted May 2002
9 *	Continue to standardize and streamline the process of receiving M+CO marketing materials, including nationwide use of "use & file" standards; establish uniform performance standards that do not exceed statutory requirements and provide training prior to their use by all the Centers of Medicare & Medicaid Services (CMS) Regional Offices (ROs.)	Adopted May 2002
10	Establish a policy wherein joint training is conducted for M+CO CMS RO and Central Office staff in one setting regarding major initiatives and issuance of significant changes in existing M+C policy.	Adopted May 2002
11	Establish a policy to provide sufficient notice to M+COs to implement major CMS information systems changes allowing M+COs to adequately budget for said changes, many of which occur when M+COs are in the midst of implementing other statutory system upgrades, such as Y2K (the year 2000) and HIPAA (the Health Insurance Portability and Accountability Act).	Adopted May 2002
12	Establish a Special Election Period (SEP) for current M+CO members who wish to enroll in a zero-premium plan offered by the same M+CO in 2002 consistent with the "lock-in" requirement.[33]	Adopted May 2002
13	Establish a policy that allows M+C plans to default members to replacement plans based on the member's primary care physician choice.	Adopted May 2002
14	Review and revise the language of its template on Medicare Health Plan Compare in situations where there is a $0 premium or $0 co-pay. The fill-in-the-blank default template language does not make sense for situations where the dollar amount is greater than $0. The result is confusing, misleading and possibly contradictory language as to financial liability.	Adopted May 2002

[31] The date has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[32] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[33] This recommendation will be relevant in later years, since the Congress delayed lock-in until 2005.

No.	Adopted Recommendation	Committee Action
15	Clarify the 36-month payment reconciliation rule to ensure that the 36-month window runs from the time an M+CO submits its information or claim rather than the time CMS acts on and enters the information or claim into the system.	Adopted May 2002
16	Publish regulations in a timely fashion. States are left in limbo or held financially responsible for unclear policies. [For example, finalize and publish the newest revision of *Medicaid and School Health: A Technical Guide* for States; clarify the policy related to payment for these services. [The "Old" version of the *Technical Guide* still references Medicaid as a payer of last resort for health-related services. The transmittal of May 2000 indicates the opposite.)]	Adopted May 2002
17	Modify the definition of "hospital property" to be only the Emergency Department and any other health facility that holds itself out to the public as being available to provide emergency or urgent care, as well as the "immediate vicinity" to the hospital property (such as the hospital lawn, parking lot, waiting room, or similar location) in situations where someone seeking emergency care is physically unable to proceed to the actual Emergency Department or urgent care facility.	Adopted May 2002 with dissent from Mr. Martin
18	Issue immediate interpretive guidance that use of community based EMS protocols, including established 911 protocols, is not a violation of the Emergency Medical Treatment and Labor Act (EMTALA).	Adopted May 2002
19*	Exclude from the purview of EMTALA, patients who are referred to the Emergency Department for diagnostic or scheduled therapeutic services, unless the diagnosis is part of the EMTALA-required screening or the treatment is part of the EMTALA-required stabilization.	Adopted May 2002
20 *	Resolve the Medicare coverage issues underlying the need for advance beneficiary notices (ABNs) to have to be provided in the Emergency Room. Consider waiving the requirement for ABNs and the associated denial of coverage in Emergency Room and other urgent care settings.	Adopted May 2002
21 *	Issue interpretive guidance that EMTALA does not apply: • In the event of an attack involving multiple casualties and where hospitals use an established disaster plan. • In the event of bioterrorism, or the threat of bioterrorism, to those hospitals directly affected and where hospitals follow a community based, regional or Centers for Disease Control (CDC) directed protocol (especially for highly contagious outbreaks like smallpox.)	Adopted May 2002
22	Review, update, and clarify in regulation and interpretive guidance what is mandated by EMTALA for the physician; clearly distinguish physician medical staff responsibilities from hospital responsibilities. In particular, CMS guidance should provide an explanation as to whether there is a recommended threshold for the application of EMTALA as it relates to the number of specialists and type of specialists on staff who are available to be "on-call" at a particular hospital. (e.g., identify safe harbors when physician specialists who are in short supply are "on call" at more than one hospital at the same time.)	Adopted May 2002
23	Require that hospitals be notified when EMTALA investigations are completed, regardless of the outcome.	Adopted May 2002
24	Make Quality Improvement Organization (QIOs) review mandatory early in the process and improve training of ROs and State Agencies (SAs) to improve performance and consistency of review of complaints. (The CMS Atlanta RO procedures should be used as a model.)	Adopted May 2002
25	Develop, fund and implement a comprehensive, ongoing communications plan that will be coordinated among the Department of Health and Human Services (HHS), CMS and its contractors, as recommended by the Advisory Panel on Medicare Education, to aggressively reach specific segments of the audience, using the appropriate channels including radio, TV, 1-800-MEDICARE, web and print media, as well as other strategies supported by research results.	Adopted May 2002
26	Continuously improve efforts to educate elderly individuals and/or individuals with disabilities approaching Medicare eligibility.	Adopted May 2002

No.	Adopted Recommendation	Committee Action
27	Add the 1-800 MEDICARE phone number and website address to the beneficiary's Medicare card.	Adopted May 2002
28	Eliminate overly burdensome Medicare Secondary Payer requirements.	Adopted May 2002
29	Research, consumer-test and evaluate the current Medicare Secondary Notice (MSN) and incorporate those enhancements that result in improved beneficiary understanding of the content. Incorporate reasons for noncoverage or denial of service on MSNs in plain language and refer beneficiaries to relevant regulations regarding the noncoverage or denial.	Adopted May 2002
30	Improve and consistently update the Medicare Plan Finder (which includes original Medicare and M+C.)	Adopted May 2002
31	Develop/implement performance standards for CMS's program of beneficiary education and communication efforts so that the program can be implemented consistently by CMS and all its agents and partners.	Adopted May 2002
32	Develop shorter versions of the Minimum Data Set (MDS) (e.g., one of the quarterly assessments forms) for Medicare & Medicaid resident assessment to the maximum extent possible. Define the specific uses of any data elements prior to retaining any element on the form as part of an overall streamlining process. Delete or revise all MDS data elements whose reliability is below generally accepted statistical standards.	Adopted May 2002
33	Clarify with interpretive guidance that the MDS is a source document and does not require supporting documentation to justify coded responses.	Adopted May 2002
34	Automate the Resident Assessment Protocols (RAPs) process at the facility level to free up more time to meet patient care needs.	Adopted May 2002
35	Update the Coverage Manual relevant to Medicare Part A; e.g., who can be covered, authorized benefit periods, breaking the spell of illness and other administrative issues.	Adopted May 2002
36	Integrate updates of the MDS Manual and Resident Assessment User [Instrument (RAI)] Guide and documentation into one manual, distribute the updated guide as soon as possible, and keep the one manual up-to-date. Revise the current manual to incorporate all interpretive guidance and answers to frequently asked questions. Keep a downloadable, up-to-date manual available on the CMS website and publish an annual print edition each year on a set date which incorporates all life-to-date regulation and guidance. Post quarterly updates on interpretive guidance to the CMS website.	Adopted May 2002
37	Continue to develop the MDS 3.0 which will include an analysis of the clinical relevancy of its contents and the capability to capture short stay assessment data, with an expected release date of 2004[34].	Adopted May 2002
38	Adopt a continuous quality improvement process to keep the MDS tool and the RAI process current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide MDS use (measure work-ups, interpretation of data quality, and interpretation of results, quality reporting, assessment of need for new measures.)	Adopted May 2002
39	Give providers joint property rights to any data submitted as part of the MDS process. [This will allow the provider to access backup copies and may reduce the need for providers to warehouse redundant manual versions of the data.]	Adopted May 2002
40	Develop facility-specific analytic reports that allow facilities to compare their own performance in relation to local, regional and national trends. Develop reports and other tools to share aggregate data with all persons.	Adopted May 2002
41	Shorten the interval from when MDS data were originally collected to when the reports of those data are made public. The older the data are, the less relevant the application and inferences to be drawn from those data.	Adopted May 2002
42	Enhance CMS's investment in education related to the use of MDS, including web-based training tools such as the Medicare Learning Network. Update the Skilled Nursing Facility (SNF) section of the Medicare Learning Network to include a detailed tutorial on	Adopted May 2002

[34] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendation	Committee Action
	MDS.	
43	Eliminate data elements that are not used for payment, quality measurement, or survey purposes for those Resident Assessments performed solely for the purpose of complying with Medicare payment requirements.	Adopted May 2002
44	Consolidate the number and timing of all MDS assessments to those that are required for care planning purposes to the maximum extent possible. Refine the timeframes for MDS assessments so that payment and quality cycles coincide and such cycles require the least number of assessments during short periods of time.	Adopted May 2002
45	Add case mix/risk adjustment to quality indicators, as appropriate.	Adopted May 2002
46	Improve the legend of key terms on the Nursing Home Compare website.	Adopted May 2002
47	Further automate the MDS process, including the design of publicly available software with "interview wizards" and other intuitive data accumulation methods.	Adopted May 2002
48	Improve the balance of nursing home comparative data available for the public to include both quality of life and quality of care measures.	Adopted May 2002
49	Standardize the investigative protocols of HHS and State survey teams. Increase training for State survey teams. Focus training on the proper interpretation of the regulatory compliance requirements placed on nursing facilities.	Adopted May 2002
50*	Use the HIPAA mandate as the basis to standardize terminology and identify common data elements used by payers, programs, providers and suppliers of care; and to determine whether RAPs are confidential and if any access protections are needed.	Adopted May 2002
51	Develop a standard instrument for the assessment of the health and functional status of patients receiving post acute services as mandated by the Benefit Improvement and Protection Act (BIPA); integrate, to the extent feasible, communication standards adopted under the Consolidated Health Information (CHI) eGov initiative as part of the development of this tool.	Adopted May 2002
52	Seek greater partnerships and outreach to the full continuum of academic medical, nursing, and other allied health care training programs in order to expose all health care professionals (not just specialists) to the value of training in gerontology and participation in interdisciplinary teams, and to the utility of clinical patient care data sets in the process of care planning.	Adopted May 2002
53*	Establish an appeal process for default Resource Utilization Group (RUG) payments with a specified timeframe for the appeal. Establish clear and reasonable rules concerning submission of the MDS instrument so that providers are not penalized with default RUG payments for legitimate, minor delays in completing an MDS assessment.	Adopted May 2002
54	Change the Outcome and Assessment Information Set (OASIS) policies to better reflect actual home health agency (HHA) operations: • Expand the time for completion of the OASIS instrument, for example from 5 days to 7 days. • Change the lock-in time for the OASIS instrument; for example, from 7 days to 14 days. (For example, HHA nurses, especially in rural areas, come to the HHA central office only once a week.)	Adopted May 2002
55	Eliminate separate form for significant change in condition when it occurs in the 5-day window of the follow up assessment.	Adopted May 2002
56	Create the option to use one OASIS form for all situations of care or change in status.	Adopted May 2002
57	Share OASIS risk-adjustment methodology with all users; make the information available on the CMS website.	Adopted May 2002
58	Provide access to the studies on the validity of OASIS data, adverse event measurements, and the University of Colorado study on OASIS quality and outcomes.	Adopted May 2002
59	Ensure that data collection efforts facilitate development of care plan. • Delete elements that are duplicative or not used for payment (including risk adjustment), quality management, or survey purposes. CMS should particularly scrutinize elements listed in Miami testimony including MO190, MO340, MO640-680, and MO780. • Eliminate OASIS encounters that are not used for payment, quality management, or survey purposes.	Adopted May 2002

No.	Adopted Recommendation	Committee Action
60	Consider the impact of HIPAA on home health agencies with respect to the timing of any changes to OASIS.	Adopted May 2002
61	Adopt a continuous quality improvement process to keep the OASIS tool current with medical practice and changing delivery systems. Establish a scientific and technical advisory panel to guide OASIS use (measure work-ups, interpretation of data quality, interpretation of results, quality reporting, assessment of need for new measures.)	Adopted May 2002
62	Field test new OASIS measures before they are put into use.	Adopted May 2002
63	Clarify the definition of "significant change." Consider using re-hospitalization as a proxy for "significant change."	Adopted May 2002
64	Conduct an independent evaluation of the cost-benefit of using the OASIS form.	Adopted May 2002
65	Create modern day electronic and on-line enrollment processes for physicians and Part B suppliers. • Immediately implement a system that allows providers to submit electronic applications via e-mail. • Develop a secure website for provider enrollment.	Adopted May 2002
66 *	Seek legislation that would require all insurance companies and other government payors to recognize the validity of the Medicare enrollment process and prohibit them from developing their own processes.	Adopted May 2002
67	Create and maintain one central repository of forms required or allowed by HHS or its principal components from all of the various HHS websites.	Adopted May 2002
68	Create a continuous review process for all forms with an eye to constantly improving and streamlining existing forms and eliminating obsolete forms.	Adopted May 2002
69	Re-design all forms and data requirements to seamlessly interface with the Information Technology (IT) architecture of HHS so as to minimize human intervention and optimize IT output. Do not publish new forms until IT issues have been addressed.	Adopted May 2002
70	Eliminate Medicare credit balance reporting.	Adopted May 2002
71	Eliminate HCFA [forms] 1513 and HCFA 1514.	Adopted May 2002
72	Incorporate [form] HCFA 2572 into CMS 855.	Adopted May 2002
73	Reduce costs and speed up administrative activities for providers, suppliers, health plans, and consumers by modernizing HHS information technology, processes, and applications: • Implement use of electronic signatures; • Implement use of e-filing; • Integrate data acquisition into IT architecture of HHS and data providers; • Maximize use of web-based transactions.	Adopted May 2002
74	Modernize the current Medicare Cost Report (MCR), make it more useful, more creative, less burdensome. • Eliminate CMS 339; fold data into cost report. • Eliminate need to file redundant manual data to support the MCR. • Modernize and speed up current audit process, settle MCRs within one year and first round appeals within six months. • Establish a method to electronically file MCRs into a central repository similar to the U.S. Securities and Exchange Commission's Electronic Data Gathering and Retrieval (EDGAR) system.	Adopted May 2002
75	Use Generally Accepted Accounting Principles-based cost reporting for providers who no longer receive cost reimbursement; continue to use a simplified and streamlined version of the Medicare Cost Report for cost-based providers.	Adopted May 2002 with dissent from Ms. Pattee.
76	Issue clear directions to carriers and State Agencies that observations made on the MDS, OASIS, and other HHS-approved survey instruments do not require redundant manual documentation to support the observations.	Adopted May 2002
77	Connect data instruments and acquisition efforts so data can be transferred and applied to another use or another site of service.	Adopted May 2002
78	Provide resources to meet the January 1, 2005 deadline set by Congress for the development of standard patient assessment instruments as mandated by BIPA. Involve providers and patients in this process.	Adopted May 2002

No.	Adopted Recommendation	Committee Action
79	Adopt protocols for joint ownership of data thus eliminating the need for manual backup copies of data.	Adopted May 2002
80	Establish a Task Force funded to address specific issues related to current practices whereby a single provider or health plan may be reviewed/ surveyed/ audited by numerous State and Federal entities (especially those under the auspices of the Secretary of HHS), none of which are required to be coordinated. The Task Force should also address regulatory oversight. The task force will be established no later than December 31, 2002 and it will have a six-month time frame for recommendations to be submitted. [35]	Adopted May 2002
81	Simplify the authorization process by adopting the Notice of Proposed Rulemaking (NPRM) proposal at (45 CFR § 164.508) that would permit a single, relatively straightforward form to cover all authorization settings. [36]	Adopted May 2002
82	Require a covered entity that obtains direct or indirect remuneration from a third party for requesting any authorization relating to use or disclosure of an individual's medical information to reveal that fact, as well as the third party source of the remuneration. (This may be achieved by including the following provisions within 45 CFR § 164.508(c)(2): "(_) If use or disclosure of protected health information by any entity pursuant to an authorization requested by a covered entity will result in direct or indirect remuneration to the requesting covered entity from a third party, a statement that such remuneration will result and identification of the third party or class of third parties who will furnish the remuneration.")	Adopted May 2002
83	Allow a covered entity to use and disclose the minimum necessary protected health information without individuals' authorizations to distribute a newsletter or similar general circulation communication to a broad cross-section of patients, enrollees or other broad group of individuals. Clarify that this activity is allowed by adding the following new rule as 45 CFR § 164.508(a)(3)(i)(C): "(C) A newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals."	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Ms. Ryan, Mr. Toby
84	Redefine activities that are *not* marketing as follows. As the NPRM proposes, add "care coordination" and "case management" to activities that are *not* marketing, and allow medical information use and disclosure without authorization for communications regarding (a) members of a provider's or health plan's network, (b) products or services, or payments for such products or services, provided by a covered entity or included in health plan benefits, (c) treatment of the individual, or (d) directing or recommending alternative treatments, therapies, health care providers, or care settings. Close loopholes in the NPRM proposal by requiring covered entities to reveal the fact and source of any third party remuneration for making "non-marketing" communications, and allowing individuals to opt out of future such communications. (This may be accomplished by adding the following provisions as new 45 CFR § 164.514(e): "(e)(1) *Standards: certain communications involving remuneration*. Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals, a covered entity that uses or discloses an individual's protected health information to communicate with that individual by any means, other than face-to-face with	Adopted June 2002; Re-Adopted September 2002 with dissent from Dr. Olsen, Mr. Toby

[35] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

[36] The Committee formulated recommendations 81-98 regarding the Privacy Rule with public input that was received prior to the issuance of both the March 27, 2002 NPRM and the August 14, 2002 Final Rule, and, hence, the Committee's recommendations may not reflect those final changes.

No.	Adopted Recommendation	Committee Action
	that individual, about any of the matters described in paragraphs (e)(1)(i)-(iii) of this section, and that receives or will receive direct or indirect remuneration from a third party for making the communication, must meet the requirements of paragraph (e)(2) of this section. "(i) The covered entity communicates with an individual to describe the entities participating in a health care provider network or a health plan network, or to describe if, and the extent to which, a product or service (or payment for such product or service) is provided by a covered entity or included in a plan of benefits. "(ii) The covered entity communicates with an individual for treatment of that individual. "(iii) The covered entity communicates with an individual for case management or care coordination for that individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to that individual. "(2) *Implementation specifications: requirements relating to certain communications involving remuneration.* Except when the communication is contained in a newsletter or similar type of general communication device that the covered entity distributes to a broad cross-section of patients, enrollees, or other broad group of individuals or is face-to-face with the individual, a covered entity that makes a communication as described in paragraphs (e)(1)(i)-(iii) of this section and that receives or will receive direct or indirect remuneration from a third party for making the communication must in the communication: "(i) Identify the covered entity as the party making the communication; "(ii) Prominently State that the covered entity has received or will receive remuneration from a third party for making the communication and disclose the name of the third party providing the remuneration; and "(iii) Provide instructions describing how the individual may opt out of receiving future such communications, and for each individual who so opts-out, avoid any future such communications with that individual.") Clarify in the rule, or at least in the preamble to the rule, that an activity that the Privacy Rule characterizes as "not marketing" may still be marketing regulated by other applicable Federal and State laws, such as Food and Drug Administration regulations, CMS rules addressing M+C materials, and the anti-kickback and anti-influencing laws (Social Security Act §§ 1128A(a)(5), 1128B(b)). HHS Office of Civil Rights (OCR) should coordinate the final "marketing" provisions of the PR with the HHS Office of Inspector General (OIG), FDA, and other appropriate Federal agencies to ensure consistency in regulatory provisions among these agencies.	
85	Clarify that incidental use and disclosure is permitted (45 CFR §§ 164.502(a), 164.530(c)) by adopting the NPRM provisions that specify that uses and disclosures reasonably incidental to permitted uses and disclosures of medical information are not violations of the PR.	Adopted May 2002
86	Clarify the provisions on informal permission for persons involved in payment related to an individual's health care, so that communications with family or others acting for an individual "not present" to resolve payment matters relating to the individual's health care, are permitted. (This can be accomplished by rewording of the first sentence of 45 CFR § 164.510(b)(3) as follows: "(3) *Limited uses and disclosures when the individual is not present*. If the	Adopted May 2002

No.	Adopted Recommendation	Committee Action
	individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care or payment related to the individual's health care.")	
87	Reconcile potential conflict between confidential communications and explanations of benefits (EOB) issuance (45 CFR §§ 164.501 ("Payment"), 164.522(b)(1)) by clarifying that a health plan may require the person demanding confidential communication to explain how the health plan can perform its payment obligations of issuing EOBs to the subscriber. Require the HHS OCR to coordinate the PRwith the rules of the Department of Labor's (DOL) Pension and Welfare Benefits Administration, which regulates Employee Retirement Income Security Act (ERISA) group health plans, in order to avoid conflicting compliance obligations for ERISA group health plans and the health insurers that administer or underwrite them. [This may be accomplished by rewording 45 CFR § 164.522(b)(2)(ii)(A) to State, "When appropriate, information as to how payment activities, including issuance of explanations of benefits to the insured under a health plan, will be handled." Another potential solution is to allow a health plan to warn in its notice of privacy practices that requests for confidential communications may not prevent the insured under a health plan from receiving other information, such as explanations of benefits for others covered by the insured's policy or benefits plan, that may alert the insured that the individual requesting confidential communications obtained health care. Yet another is to permit a health plan to inform an individual requesting confidential communication that the individual may have to pay for the care to avoid the health plan providing information to the insured through other explanations of benefits or similar communications that may alert the insured that the individual obtained health care in confidence.]	Adopted June 2002; Re-Adopted September 2002 with dissents from Dr. Olsen, Ms. Ryan
88	Delete the endangerment requirement at 45 CFR §§ 164.524(a)(3), (4), (d)(2) and leave it to the health care professional's judgment, exercised in the best interest of the individual or others, whether requested protected health information should be made available to an individual or the individual's personal representative. Continue to grant the individual or the individual's personal representative denied access, based on that exercise of professional judgment, the right to have another professional review the access denial. Allow the explanation for the denial to be, simply, "Information has been withheld based on the judgment of a qualified health care professional." [The revised rule and procedures would thus state: "§ 164.524(a) . . . "(3) *Reviewable grounds for denial*. A covered entity may deny an individual or an individual's personal representative access to specific protected health information concerning the individual if a licensed health care professional has determined, in the exercise of professional judgment, that providing access to that protected health information is not in the best interest of the individual or others. The individual or the individual's personal representative has the right to have such denial reviewed in accordance with the procedures of paragraph (d)(4) of this section. "[Delete paragraphs (a)(3)(i)-(iii) and (a)(4) of this section.] "(b) *Implementation specifications: requests for access and timely action. . . .*	Adopted June 2002; Re-Adopted September 2002 with dissents from Dr. Olsen, Ms. Ryan and Mr. Toby

No.	Adopted Recommendation	Committee Action
	"(2) *Timely action by the covered entity*. (i) . . . the covered entity must act on a request for access no later than 30 days after receipt of the request as follows. . . . "(B) if the covered entity denies the request, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d) of this section. . . . "(d) *Implementation specifications: Denial of access*. If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements. . . . "(2) *Denial*. The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain: "(i) The basis for the denial. If the denial of access is in accordance with paragraph (a)(3) of this section, it is sufficient to state, "Information has been withheld based on the judgment of a qualified health care professional." "(ii) If the denial is in accordance with paragraph (a)(3) of this section, a statement of the individual's review rights under paragraph (d)(4) of this section, including a description of how the individual may exercise such review rights. "(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii) "(4) *Review of denial requested*. If the individual or the individual's personal representative requests review of a denial of access under paragraph (a)(3) of this section, the covered entity must designate a licensed health care professional to review the decision to deny access. This designated reviewing official must not have been directly involved in the denial, and must be qualified by training or experience to make an informed evaluation whether withholding the protected health information to which access has been denied is in the best interest of the individual or others. The covered entity must promptly refer the request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable time, whether to deny or grant the access requested based on the designated reviewing official's professional judgment, exercised in the best interest of the individual or others. The covered entity must promptly provide written notice to the individual or the individual's personal representative of the determination of the designated reviewing official, and take all action required by this section to carry out the designated reviewing official's determination."]	
89	Allow an additional year for covered entities to conform pre-existing contracts with business associates to the PR's requirements, and issue the model business associate terms suggested by the NPRM.	Adopted May 2002
90	Modify the PR to specify that a covered entity serving as a business associate must comply with each provision of 45 CFR § 164.504(e)(2) applicable to that business associate relationship. Continue to require that the covered entity specify in writing the uses and disclosures that the business associate covered entity is allowed to make, as required by 45 CFR § 164.504(e)(2)(i). [This provision is needed because a business associate is permitted to use and disclose the protected health information of the covered entity it serves only as that covered entity allows.	Adopted May 2002

No.	Adopted Recommendation	Committee Action
	This approach can be implemented as follows. Revise 45 CFR § 164.502(e)(1)(iii) to state: "(iii) A covered entity acting as the business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e) of this subpart if the business associate covered entity violates any of the provisions of § 164.504(e)(2) of this subpart, including any use or disclosure of the protected health information of the covered entity on whose behalf the covered entity business associate is acting that is inconsistent with the uses and disclosures of such information specified in writing as required by paragraph (e)(2)(i) of this section by the covered entity on whose behalf the business associate covered entity is acting." Revise 45 CFR § 164.502(e)(2) to state: "(2) *Implementation specification: satisfactory assurance*. A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section by: "(i) For a business associate who is also a covered entity, specifying in writing the permitted and required uses and disclosures of the covered entity's protected health information by the business associate in compliance with § 164.504(e)(2)(i) of this subpart. "(ii) For a business associate who is not a covered entity, obtaining a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e) of this subpart."]	
91	Adopt the NPRM proposal at (45 CFR §§ 160.202, 164.502(g)) to clarify that parents' access to the medical information of their unemancipated children is controlled by State law, and when State law is silent, by the covered entity's professional judgment.	Adopted May 2002
92	Adopt the NPRM proposal at (45 CFR § 164.504(a)) to remove "primary" from the hybrid entity definition and give any covered entity with non-covered functions the option to designate itself a hybrid entity. [By adopting this proposal, the covered entity will be required to identify each of its operations that perform covered functions and subject these health care components, as well as each component that serves the health care components in a business associate capacity, to PR compliance. The effect will be that the health care components, and the components serving them in a business associate capacity, may not disclose their protected health information to, or allow their protected health information to be used by, non-health care components unless the PR allows such disclosure or use. For example, a health care component will not be allowed to disclose its protected health information to the covered entity's human resources personnel performing non-covered employment functions. It also means that individually identifiable health information held by the covered entity's non-health care components (*e.g.*, health information in the human resources department is not protected health information subject to the PR.)]	Adopted June 2002; Re-Adopted September 2002 with dissents from Dr. Olsen and Mr. Toby
93	Adopt the NPRM proposal at [45 CFR § 164.501 ("Protected Health Information")] that would exclude employment records from the protected health information definition.	Adopted May 2002
94	Adopt the NPRM proposal at (45 CFR § 164.504(f)) to explicitly state that a health plan may disclose enrollment data to the employer or other sponsor of the group health plan, even if the sponsor does not qualify under the PR to perform plan administration functions.	Adopted May 2002
95	Adopt the NPRM proposal at (45 CFR § 164.514(b)(2)(i)(R)) that would make clear that a re-identification code or key under (45 CFR § 164.514(c)) does not have to be deleted to de-identify data.	Adopted May 2002
96	Clarify the de-identification safe harbor knowledge requirement (45 CFR § 164.514(b)(2)) by making clear that "other information" must be available outside the covered entity and by clarifying the meaning of "actual knowledge" in the corporate	Adopted May 2002

No.	Adopted Recommendation	Committee Action
	context. (This may be accomplished by revising 45 CFR § 164.514(b)(2)(ii) as follows: "(ii) The covered entity determines, after documented inquiry of those of its components that may be reasonably expected to know, that it has no actual knowledge that the information could be used alone or in combination with other information available outside of the covered entity to identify an individual who is a subject of the information.")	
97	Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the privacy standards, and for compliance with those modifications and additions as follow: • Publish final modifications, additions, and deletions to privacy standards as final rules in the *Federal Register* on the same, pre-set calendar date each year (for example, Dec. 1 or nearest business day before that date.) • Establish a six -month compliance date for routine modifications and additions to privacy standards. • Specify a longer compliance period for major privacy standards changes that require the industry to have very long planning periods. [This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in others may be far-reaching.][37]	Adopted May 2002
98	Establish a PR advisory panel either within the National Committee on Vital and Health Statistics or as a separate advisory committee or task force, to concentrate on improving the operation and consumer privacy protections of the PR and to advise HHS on the modification, additions, and deletions to the PR's standards and implementation specifications for the defined annual PR Modification cycle. The advisory panel or task force should be comprised of health industry representatives, patients, and health plan enrollees with significant operational experience in the delivery and financing of health care and representative of various government agencies, including FDA, DOL, OIG, Department of Justice, State Medicaid programs, etc. that regulate activities affecting health care delivery or financing.	Adopted May 2002
99	CMS should eliminate the E&M Documentation Guidelines.	Adopted May 2002 with dissent from Dr. Olsen
100	Encourage SNFs certified to participate in Medicare to use the new shorter assessment form [called the Medicare Payment Assessment Form] to update a Medicare beneficiary's condition on days 5, 14, 30, 60 and 90 of the person's stay in the nursing home. Maintain the policy that SNFs complete the full MDS to assess resident status on admission, annually and upon significant change in resident status thereafter. (Note, the requirement that the admission MDS is to be completed no later than l4 days after the resident's admission would continue in force.)	Adopted June 2002
101	Consider the efficacy of making the collection of OASIS mandatory for Medicare patients only.	Adopted June 2002 with dissents from Dr. Olsen, Mr. Fay, and Mr. Bloom
102*	Establish incentives to encourage State Medicaid programs to discontinue requiring [forms] HCFA 1513, HCFA 1514, HCFA 1561, HCFA 2572 and other forms no longer used by CMS.	Adopted June 2002

[37] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

No.	Adopted Recommendation	Committee Action
103	Expand the J Code system to more accurately define the package size used. If available package sizes are 100 mg, 200 mg, and 1 gram, have separate codes for each of those sizes, with corresponding reimbursements.	Adopted June 2002
104	Further clarify the HIPAA final transaction rules to allow providers to make changes in the event the National Drug Code (NDC) system is going to remain a part of the initial HIPAA transactions codes implementation.	Adopted June 2002
105	Clearly define covered drug products instead of broadly defining what may qualify as self-administered.	Adopted June 2002
106	Use patient-specific modifiers that may move drugs into a covered category for patients with limited mobility and/or capability to understand therapeutic schedules.	Adopted June 2002
107	Implement a drug coding system that is standard, updates electronically, and specifically states the product administered. (Currently the only such coding system that exists is the NDC coding system.)	Adopted June 2002
108	Follow the General Accounting Ofice (GAO's) February 2002 recommendation that CMS NOT establish its own separate review program, distinct from State efforts, to ensure the accuracy of MDS data for payment purposes. Reorient CMS's proposed MDS accuracy program and confine its monitoring activities to determining the adequacy of each State's efforts to ensure MDS accuracy and providing guidance and technical assistance to individual States, as needed.	Adopted June 2002
109	Improve CMS's oversight of contractor customer performance by establishing a customer satisfaction survey process to be conducted by an organization independent of CMS and its contractors. • Include periodic (e.g., quarterly or semi-annual) survey events along with a continuous customer feedback process. • Include different approaches for beneficiaries, physicians, providers and suppliers. • Publish customer satisfaction survey results of each contractor in the media and on the CMS and Medicare.gov websites. • Include the results in the contractor performance scores. Use these results in establishing the bidding schedule and as a major consideration in contract awards.	Adopted June 2002
110 *	Consolidate existing definitions of rural into one communicable definition. [Currently rural can mean one thing for a hospital and another for a rural health clinic.]	Adopted June 2002
111	Disaggregate data describing rural healthcare delivery from data describing urban healthcare delivery to ensure accurate representation of resources and expenses for the purposes of rule making and rate setting.	Adopted June 2002
112	Eliminate the ceiling regarding the maximum number of surgeries a rural hospital can perform in order to bill Part A for Certified Registered Nurse Anesthetist (CRNA) services instead of Part B, to eliminate the burden of having to get Part B provider numbers for rural CRNA's.	Adopted June 2002
113 *	Establish a Part A fee schedule for CRNA services. [This schedule could be used to reimburse rural hospitals in lieu of the pass-through cost of CRNA services.]	Adopted June 2002
114	Allow hospitals, skilled nursing facilities and other affected entities to file an annual, renewable three-year geographic reclassification application. Consult with the Office of General Counsel and industry legal experts to determine if the Medicare, Medicaid and SCHIP BIPA of 2000 does indeed permit the filing of renewable, three-year geographic reclassification applications. Accept the first renewable application by September 1, 2003 if it is determined that three-year renewable geographic reclassification applications are permitted by statute.[38]	Adopted June 2002
115 *	Address rural workforce issues • Consider continuance of "hold harmless" provisions under the Prospective Payment System for ambulatory services • Recognize Advanced Registered Nurse Practitioners as providers of services	Adopted June 2002

[38] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendation	Committee Action
	• Retain the State's statutory flexibility regarding use of CRNAs • Recognize the need for educational support for preparation of rural healthcare providers • Recognize the impact of tighter immigration regulations on access to foreign physicians and immigrant entry-level caregivers and the need to work with rural healthcare providers to resolve these issues.	
116	Develop a pilot certification survey process for Critical Access Hospitals (CAHs) that would entail a single survey to examine all aspects of the hospital's operations and allied health services.	Adopted June 2002
117 *	Develop a legislative proposal with Congress for a single certification survey process for all providers of rural health services, including hospitals, SNFs, HHAs, rural health clinics, community health centers, etc., based on the results of the single survey process for CAHs.	Adopted June 2002
118	Urge the National Advisory Committee on Rural Health to advise HHS on a process whereby HHS works with knowledgeable representatives of rural America to analyze the impact of a new statute or regulation on the rural delivery system before it is enacted.	Adopted June 2002
119 *	Develop a legislative proposal with Congress to address the current fragmented approach to rural Medicare payment policy (e.g., Sole Community Hospitals, CAHs, bonus payments for rural primary care physicians, etc.) with an eye towards replacing this fragmented approach with a system that recognizes the unique operating characteristics of rural providers in all settings.	Adopted June 2002
120 *	Limit the application of the Medicare's Home Health COPs based on certain payers (e.g., apply to Medicare patients only) and service criteria (e.g., the criteria would exclude services that do not meet the definition of "home health services" in the Social Security Act Section 1861, such as those that are custodial in nature or considered personal care and may not result from a signed physician order.)	Adopted June 2002 with dissent from Dr. Olsen
121	Revise the CMS Interpretive Guidance on Medicare's HHA COPs (the State Operations Manual (SOM) – Provider Certification, Section 2183,"Separate Entities") to give all agencies more flexibility in managing their operations, such as the requirements for separate policies and procedures for admission, separate clinical records, separate licensure (unless required by the State), separate timesheets and personnel records, and separate budgets. [The Interpretive Guidance contains directions to State surveyors for recognizing and qualifying an organization as a "separate entity" so that they can properly certify that HHA meets Medicare's COPs. The surveyors would not apply the COP requirements to the patients served by the "separate entity."]	Adopted June 2002 with dissent from Dr. Olsen
122	Establish a coordinated annual schedule for CMS-related on-site audits/reviews of M+COs to ensure that oversight activities are coordinated to the greatest extent possible for those M+COs that wish to have their routine periodic and scheduled reviews take place at the same time. [Unannounced reviews or visits would not be affected by this provision.]	Adopted June 2002
123	Establish a process for making timely changes to the standardized Summary of Benefits (SB) language so that beneficiaries can rely on it to make informed choices. Permit limited variations from the standardized language when they are needed for accuracy and are made in a way that does not undermine the utility of the SB for plan-to-plan comparison.	Adopted June 2002
124	Examine Social Security Administration (SSA) disenrollment forms and Medicare & You Handbook information to ensure that the text does not stimulate an unintended disenrollment that triggers the "lock-in."[39]	Adopted June 2002
125	Explore the feasibility of permitting members of employer group health plans or individuals who have access to a personal computer to enroll and disenroll electronically from M+C plans, and begin a pilot to test said procedures, respecting security, privacy, and other related matters.	Adopted June 2002
126	Clarify the policy that in the event that a M+CO becomes insolvent, and can no longer	Adopted June 2002

[39] This recommendation will be relevant in later years, since the Congress delayed lock-in until 2005.

No.	Adopted Recommendation	Committee Action
	pay the provider network, the beneficiary is still responsible for any pre-determined obligations (e.g., co-pays, etc.) but should not be balance-billed for any unpaid services beyond that obligation.	
127	Make the changes necessary to implement the M+C enrollee health risk adjustment methodology with the M+C program on a budget neutral basis, without increasing or decreasing total funding for the M+C program as intended by Congress.	Adopted June 2002 with dissent from Ms. Ryan, Mr. Fay, Ms. Pattee, Dr. Olsen and Ms. Martin
128	Reduce the number of pages of referring telephone numbers in the next publication of the Medicare & You Handbook by focusing on 1-800 MEDICARE so as to avoid overwhelming readers. Ensure that all transferred callers from 1-800-MEDICARE are connected expeditiously with a "live" person at the connected number. Furthermore, work with consumer testing groups to determine the best content and organization of the Medicare & You Handbook, if not currently doing so.	Adopted June 2002
129	Improve communication between CMS and States, including the clarity and consistency of Medicaid policy interpretations across CMS by conducting centralized training for all RO and CO staff to ensure uniformity.	Adopted June 2002
130 *	Seek administrative solutions within statutory parameters to reduce Transitional Medical Assistance (TMA) reporting requirements from quarterly to annually, until such time as the statutory parameters are addressed. [Currently, families receiving transitional Medicaid coverage must report requested information quarterly, and they lose eligibility if the information is not submitted.]	Adopted June 2002
131	Define limits of EMTALA by clarifying that EMTALA requirements end when a qualified medical person has made a decision: • that no emergency exists; • that an emergency exists and the patient is stabilized; • that an emergency exists which requires transfer to another facility where the EMTALA obligation rests with the transferring hospital until arrival at the receiving hospital; or • that an emergency exists and an unstable patient (who) is admitted to the hospital has been stabilized.	Adopted June 2002
132	Create an Emergency Services Cooperative Project that would follow the format of the Diabetes and Cardiovascular Quality Improvement Project. This should be developed and implemented with a scientific and technical advisory board of emergency physicians, hospitals, first responders, emergency transportation specialists, consumers and other advisers. This group should also guide development of future regulations that would assure availability of effective emergency services in all parts of the country. This group would include on-call physicians (medical and surgical specialists who provide care for emergencies) as part of the scientific and technical advisory board for the Emergency Services Cooperative Project. In the future this group should take on thorny issues such as reimbursement mechanisms for EMTALA related services when patients don't have insurance; foster appropriate consultation with and involvement by QIO; appropriate due process for hospitals and health care professionals before CMS can issue a public notice of termination and proceed with a termination letter.	Adopted June 2002
133	Clarify the "prudent layperson" concept as per the EMTALA NPRM as follows: • The term "prudent" has a commonly understood meaning, and we would refer the reader to the general dictionary definition to this term. • A "layperson" refers to an individual with an average knowledge of health and medicine, as the definition of "emergency medical condition" states.	Adopted June 2002
134	Expand contractual relationships to community-based organizations (in addition to SHIP programs, organizations with whom Regional Education About Choices in Health (REACH) currently works) for translation services, information/education services, and outreach to individuals with Limited English proficiency (LEP), persons with disabilities, and beneficiaries in rural areas. Consider the Request for Proposal (RFP) process as a means of establishing these relationships.	Adopted June 2002

No.	Adopted Recommendation	Committee Action
135	Improve the accuracy and effectiveness of beneficiary counseling and assistance programs (e.g., State Health Insurance Assistance Program [SHIPs]) by fully integrating them into regional and local outreach activities and by providing consistent training to these programs. Training programs should be based on national standards with implementation tailored to community needs.	Adopted June 2002
136*	Encourage and/or incentivize State Medicaid plans to provide reimbursement to community agencies providing education and outreach activities.	Adopted June 2002
137	Simplify beneficiary forms, use plain language in forms, and use peer focus groups to rigorously re-test the clarity of communication on an ongoing basis. Test the effectiveness of targeting communications literacy to the 4th grade level. (Currently, Medicare policy targets a 6th grade literacy level.)	Adopted June 2002
138*	Simplify the Medicare application using plain language, and encourage States to develop their own simplified, universal application for Medicaid and other services.	Adopted June 2002
139	Continually evaluate and improve education and communication strategies to ensure that beneficiaries find materials easy to access and understand so they can make informed decisions about their rights, options and obligations.	Adopted June 2002
140	Implement education and training of intermediaries and carrier call centers regarding the rules for disclosing beneficiary-specific information to others (as covered in Transmittal AB-01-87.) Publish these guidelines in plain language for the general public on the medicare.gov website.	Adopted June 2002
141	Enhance provider education efforts by ensuring that comprehensive communication plans are coordinated among HHS, CMS, and its contractors, to aggressively reach the various provider communities (including physician, nurses and other provider groups.) These communication plans should include how to use local and national educational campaigns and advisory committees in the most effective way possible and be responsive to the needs of all provider groups.	Adopted June 2002
142	Simplify communications to providers using plain language and using formats that are accurate and easy to use by the provider groups on an ongoing basis. Target communications appropriately and include an executive summary of key points in all bulletins, updates, and instructions. (For example, develop a simplified "executive summary" set of instructions for physicians and staff to use the new advanced beneficiary notices.)	Adopted June 2002
143	Maximize the use of technology-based educational initiatives (for example, MedLearn), targeting content to the different types of providers, including non-physician providers, and suppliers of care.	Adopted June 2002
144	Consult with advisory panels or groups of providers to provide real-time review of new communication strategies or materials in a proactive manner. Use focus groups of the intended audiences to rigorously test clarity of communications and educational programs.	Adopted June 2002
145	Ensure that interpretations of regulations are consistent within all manuals and that every program memorandum clearly describes the modifications or introductions of regulations. Require carriers to give answers based on regulations and CMS guidelines and not on their own interpretations. Eliminate penalties or denial of payment to providers for errors due to incorrect advice from carriers or fiscal intermediaries.	Adopted June 2002
146	Continuously improve the development of a central repository of information (i.e., MedLearn) so that general information for providers, and rules/regulations are disseminated from CMS and not individual carriers, while being cognizant of regional sensitivities.	Adopted June 2002
147	Survey fiscal intermediaries (FIs) and carriers and publicize the results of what are discovered to be the contractors' "best practices" relating to provider education and communication.	Adopted June 2002
148	Compile, publish, and distribute widely a yearly report of provider best practices to serve as guidance for compliance. Give specific emphasis to best practices of rural health programs, clinics or providers among the rural health care community using most effective national and regional outreach methods. Periodically focus CMS teleconferences and listening sessions with various communities of interest on sharing	Adopted June 2002

No.	Adopted Recommendation	Committee Action
	best practices addressing problematic rules and regulations.	
149	Ensure that carriers are meeting with the medical community and stakeholders when systemic problems are identified, and that such meetings are used as a basis for provider education programs.	Adopted June 2002
150	Require carriers/ FIs to report the specific reasons for their denial of claims in plain language, explain what additional information is needed, and reference the specific regulation, policy memorandum or local medical review policy (LMRP), upon which the denial was based. Appeals to decisions should be reviewed and responded to within 45 days.	Adopted June 2002
151	Conduct outreach with the hospice and nursing home industries so that both better understand how Medicare beneficiaries living in nursing facilities can access hospice services	Adopted June 2002
152	Develop and continuously improve provider educational initiatives programs to address systemic misperceptions and confusion that exist in the home care and long-term care industry about CMS's policies and requirements (e.g., on OASIS, MDS, and homebound status.)	Adopted June 2002
153	Involve all stakeholders early in the course of policy development to ensure that subsequent regulations and interpretations will be understandable and workable in diverse settings.	Adopted June 2002
154	Assess the effectiveness and publish results of the evaluations of provider educational materials, including but not limited to the new Resident and New Physician Training Manual.	Adopted June 2002
155	Establish a workgroup to evaluate the impact and feasibility of standardized medical review policies.	Adopted June 2002
156	Streamline the frequency of communication output, particularly rules and regulations, by ultimately moving to an annual publication of CMS regulations (Medicare Provider Manual) with quarterly updates for new technologies, treatments and coverage decisions. Make this available online and in easy to update paper format.	Adopted June 2002
157	Provide assistance for small rural communities to learn and apply for competitive requests for proposals. Provide account service representatives to rural health clinics/providers.	Adopted June 2002
158	Market/publicize regional technical assistance workshops and train-the-trainer programs to assist rural health care providers and programs in each State.	Adopted June 2002
159	Intensify outreach efforts to educate rural health clinics and providers about the specific programs that focus on rural communities and invest in rural "best practices." Develop a rural health care section on relevant HHS websites for providers that will include all appropriate resources, technical and financial assistance programs, and best practice models for rural communities.	Adopted June 2002
160	Develop models to educate people from rural communities to become health care practitioners and provide incentives for these practitioners to remain in their own rural communities.	Adopted June 2002
161	Convene focus groups to continue to improve the clarity of the ABN for both beneficiaries and providers. Emphasis should include the minimizing of any question of medical judgment.	Adopted June 2002
162	Continue to improve the LMRP web site so it is more user-friendly.	Adopted June 2002
163 *	Evaluate the potential for CMS to develop an automated prior authorization system that could, using computer edits similar to those used by insurance companies in their current claims processing systems, efficiently determine whether most claims will or will not be covered; develop a pilot program to test use of such a system in Medicare; determine the extent to which additional resources beyond computer edits may be needed for accurate prior coverage determinations; implement and evaluate the pilot program, focusing on the benefits perceived by beneficiaries and providers and the potential to minimize costs to the program; and based upon lessons learned in the pilot program, develop and implement a full national Medicare system to furnish prior coverage determinations to both beneficiaries and providers.	Adopted June 2002

No.	Adopted Recommendation	Committee Action
164	Exclude from Medicare LMRP those diagnostic services ordered by a qualified medical professional when medically necessary pursuant to satisfying the Hospital's EMTALA obligations; and require fiscal intermediaries (FIs) and carriers to pay for diagnostic services when ordered and provided in connection with satisfying the hospital's EMTALA obligation.	Adopted June 2002
165	Simplify and clarify the Clinical Laboratory Improvement Act (CLIA) requirements using plain language whenever possible to assist laboratory and physician office laboratory (POL) staff in understanding and complying with CLIA guidelines.	Adopted June 2002
166	Provide information to POLs about training opportunities by the State survey agencies and accrediting bodies such as the College of American Pathologists (CAP) and the Commission on Office and Laboratory Accreditation (COLA) to assist with interpretation and implementation of new CLIA requirements.	Adopted June 2002
167	Update and make more user friendly CMS's CLIA website; include links to the Centers for Disease Control and Prevention's National Laboratory Training Network.	Adopted June 2002
168	Include a plain language version of both CDC's the CLIA requirements as well as a basic laboratory practices document tailored to the POL's test system menu for moderate complexity tests, as part of the CLIA application package.	Adopted June 2002
169	Help laboratories to interpret the new CLIA requirements by offering training and simplified guidelines at meetings of laboratory professionals, accreditation bodies and medical organizations.	Adopted June 2002
170	Develop protocols of compliance surveys for waived POLs that use criteria established in consultation with accrediting agencies and physician organizations. Perform compliance surveys when indicated on waived laboratories according to CLIA guidelines and using criteria established in consultation with accrediting agencies and physician organizations.	Adopted June 2002
171	Modify the Alternate Quality Assessment Survey (AQAS) self survey form as an educational tool to facilitate the survey and certification process.	Adopted June 2002
172	Increase the number of POL representatives serving on the Clinical Laboratory Advisory Committee (CLIAC) to more accurately reflect the number of POLs being regulated.	Adopted June 2002
173	Develop an educational brochure for POLs containing plain language interpretation of the regulatory requirements by having CMS and CDC collaborate.	Adopted June 2002
174	Provide open forums with professional, medical, and accreditation laboratory organizations to solicit feedback on ways to improve outreach to POLs and to increase understanding of the CLIA program among physicians.	Adopted June 2002
175	Solicit interest in developing an educational "Clearinghouse" on the CLIA website that includes a multimedia educational program package from interested parties including: CMS, other Federal agencies, professional, medical and accreditation laboratory organizations, and the CLIAC. Design methods for evaluating the effectiveness of educational programs.	Adopted June 2002
176	Collaborate with States and private laboratory organizations to develop and promote self-assessment tools for laboratories, as well as other types of educational programs. Include in these efforts an evaluation of the effectiveness of such educational programs.	Adopted June 2002
177	Stress to CMS staff the importance of collegiality and clarity in communication with providers, and incorporate these factors into employee performance evaluations.	Adopted June 2002
178	Address program integrity problems with a general understanding that most providers want to comply with program rules, and that targeted education is the best way to address problems. Reserve other approaches for instances when targeted education efforts have failed or there is clear evidence of intentional misconduct.	Adopted June 2002
179	Strengthen efforts to increase and improve provider education on an ongoing basis, with a new emphasis on incorporating feedback from providers into continuous quality improvement efforts. Develop mechanisms to routinely obtain and evaluate such feedback, such as focus groups, surveys, and other methods.	Adopted June 2002
180	Ensure that CMS has staff with well-developed talent for explaining complex matters in plain language, and work with policy experts to ensure that written communications to providers are clear, concise, and collegial. Hire and/or train staff extensively to achieve the relatively high skill levels needed to explain complex Medicare policies clearly.	Adopted June 2002

No.	Adopted Recommendation	Committee Action
181	Eliminate the practice of having contractors and ROs rewrite materials from CMS's CO, allowing exceptions only when required by unique local conditions.	Adopted June 2002
182	Publish annual reports that establish a baseline and track progress over time of efforts to improve the clarity and collegiality of communications.	Adopted June 2002
183	Evaluate the impact of newly revised materials to determine if they reduce the number of beneficiaries who make inappropriate decisions based on a misunderstanding of their rights and options.	Adopted June 2002
184	Evaluate whether instructing newly eligible beneficiaries to call 1-800-MEDICARE for questions about Medicare Part B eligibility is more effective in helping them to become accustomed to this resource than instructing them to call a toll free SSA online number, which is current practice.	Adopted June 2002
185	Set a defined schedule (45 CFR § 160.104) for issuance of final modifications, additions, and deletions to the transactions standards, and for compliance with those modifications and additions as follow: • Publish final modifications, additions, and deletions to transactions standards as final rules in the *Federal Register* on the same, pre-calendar date each year (for example, Dec. 1 or nearest business day before that date.) • Establish a six-month compliance date for routine modifications and additions to transactions standards. • Specify a longer compliance period for major transactions standards changes (e.g., replacement of a clinical code set) that require the industry to have very long planning periods. • Investigate development of a process to identify "minor" modifications and expedite their publication (perhaps via abbreviated rule making) in recognition of the opportunity for public input that is already afforded by the industry standards development process, again based on specified publication and effective dates. [This recommendation assumes that the nature of modifications will vary from year to year. In some years, changes may be minor in nature, while in others may be far-reaching because of proposals for new transactions, replacing clinical code sets, etc.][40]	Adopted June 2002
186	Require the definition of every standard transaction (45 CFR §§ 162.1101 162.1801) to include a "sender" specification and a "receiver" specification. (For example, revise the "health care claims status" and "referral certification and authorization" standard transactions to add "sender" and "receiver" requirements to their definitions.)	Adopted June 2002
187	Eliminate or define in a useful manner the meaning of "Within the Same Covered Entity" (45 C.F.R § 162.923(a).) [For example, if the intent of this provision is to require that transactions between health care components doing different covered functions that are part of the same corporate entity ought to be in standard formats, then apply the concepts of "hybrid entity," "covered functions," "multiple-function covered entity," and "health care components" (now applicable only to the HIPAA Privacy Rule) to all of the HIPAA rules, including the Transactions Rule. The "within the same covered entity" provision could then be redefined to apply only to transactions that are between a covered entity's health care components that do different covered functions.]	Adopted June 2002
188	Issue clearer rules, including more meaningful compliance guidance, for covered entities regarding conduct of Direct Data Entry (DDE) Transactions (45 CFR § 162.923(b).)	Adopted June 2002
189	Work with OMB to recognize that budget neutrality is measured across Medicare and all benefit programs under the purview of the Secretary of the HHS, not solely Medicaid. A specific situation to apply the recognition is when determining whether waiver services are cost-effective, CMS should uniformly clarify or adopt the policy that "cost-effective"	Adopted June 2002

[40] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

No.	Adopted Recommendation	Committee Action
	means waiver services will cost no more to the Medicare & Medicaid programs combined than the combined costs of providing Medicare & Medicaid services on a fee-for-service basis to the same population.	
190	Give States greater flexibility in developing their programs by stating the purpose of the program (for example, providing health care for low-income individuals) and giving the States the ability to design their own program, in compliance with Federal law, while holding States accountable for achieving the outcomes in accordance with pre-established criteria. (Do not specify how States should meet those criteria.)	Adopted June 2002
191	Work with States when drafting State Medicaid Letters and solicit States' input prior to the letter being formally issued.	Adopted June 2002
192	Convene by September 1st, 2002 with recommendations by July 1st, 2003 and a pilot ready to implement by September 1st, 2003, an inter-agency working group consisting of CMS, State Medicaid Directors, and the SSA to work on an improved system for timely and accurate identification, enrollment, and notification of dual eligibles.[41]	Adopted June 2002
193*	Identify the "best practices" of States which have been most successful in identifying and enrolling dual eligible beneficiaries (QMBs, SLMBs, QI-1s, QI-2s), including through electronic data matches, and encourage through incentives, use of those best practices in other States that are not as successful. Develop pilot studies and other demonstrations of innovative methods to integrate Medicare & Medicaid data on a near real time basis, so that States could be provided continuous ability to access and analyze their dual eligibility data on a command basis.	Adopted June 2002
194	Institute in those 15 States where there is no electronic information exchange to identify dual eligibles, data match agreements between the State, and CMS and/or SSA. Until those data match agreements have been operationalized, develop or refine interim working agreements between States and CMS and/or SSA to ensure timely notification about dual eligibility and enrollment. Work to continuously improve the quality and accuracy of the Medicaid eligibility data States bring to CMS and/or SSA, for new and existing electronic information exchanges to identify and enroll dual eligibles.	Adopted June 2002
195	Determine what barriers exist to State Medicaid Agencies complying with Federal timelines for enrolling qualified Medicare beneficiaries into premium assistance programs, and seek remedies (e.g., best practices for technical problems, information technology improvements, etc.) to remove those barriers. (The timelines apply only after an individual has filed an application through the State Medicaid Agency.)	Adopted June 2002
196	Institute immediately a policy requiring States to exempt lump sum Medicare Part B premium refunds, currently allowed to be deducted from the Social Security benefit payments of a dually eligible beneficiary during the period in which the beneficiary's *initial* Medicaid eligibility is being determined, from being counted as an asset in determining the beneficiary's continuing eligibility for Medicaid.	Adopted June 2002
197 *	Look at States that have enacted a single enrollment form for all eligible programs such as the District of Columbia. Develop a simplified, model, "one-stop-shop" application form that constitutes a formal beneficiary enrollment into all eligible Federal/State entitlement or assistance programs (for example: Medicaid, food stamps, Women Infants and Children Program (WIC), Housing, etc.). To the maximum extent possible, work with relevant agencies to standardize the form in order to develop an electronic enrollment process. Immediately have HHS look at those State programs that are most successful in enrolling dual eligible beneficiaries into all eligible Federal/State entitlement or assistance programs (especially those programs under the auspices of the Secretary of HHS.)	Adopted June 2002
198	Determine if States provide assistance to individuals who require assistance to complete beneficiary enrollment applications for Federal/State entitlement or assistance programs, consistent with applicable Federal, State and local laws, requirements, and established	Adopted June 2002

[41] One of these dates has already passed. The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendation	Committee Action
	policies, including but not limited to, those regarding individuals with LEP, and the Americans with Disabilities Act. Work with States to eliminate any technical barriers they may encounter to meeting those requirements and share best practices that demonstrate effective methods of doing so.	
199	Work in coordination with States on development of appropriate educational materials for dual eligibles that are equal in quality to those published for all Medicare beneficiaries, to assist dual eligibles in understanding the programs (including the core set of Federally mandated Medicaid services) to which they are entitled and their financial responsibility in those programs. Use these materials as part of outreach efforts with this population.	Adopted June 2002
200	Evaluate for best practices the State of Connecticut's 211 system for beneficiary information called "Info Line" (www.infoline.org.) Determine the extent to which other States are using this model and encourage the use of systems like "Info Line" by States as a model for all Medicare & Medicaid beneficiaries.	Adopted June 2002
201	Clarify in the SOM section(s) dealing with "Medicare-Medicaid Certification - Distinct Part Designation", that any reference to particular "examples" (mentioned either in relevant Instructions, Survey Procedures, Interpretive Guidelines, or Forms) is intended only to be EXEMPLARY of how compliance may be achieved, but does not constitute the only configurations that are allowed for compliance with the statute or regulations. Clarify for State surveyors, that in the absence of a facility complying with one or more examples that are mentioned, the facility must still be able to demonstrate how it complies with the regulation or statute. Provide guidance and training to surveyors and providers. Follow-up and monitor consistency in application. (Recommendation refers to just SNF/nursing facility [NFs].)	Adopted June 2002
202*	Require FIs to render decisions on demand bills within 45 days after receiving all medical records documentation required by the FI to support the original decision made by the SNF Provider. If the FI decision is not rendered by 90 days, require FIs to pay the SNF automatically. Require administrative law judges (ALJs) to render a decision within a 90-day period of time after an appeal is filed at the ALJ level. Allow payment without "prejudice" during the appeals period.	Adopted June 2002
203	Revise the Medicare & Medicaid cost reports to reflect the current purpose and use of these two separate documents. The data should be sufficient to create, as required by Congress, a SNF wage index, appropriate market basket update and other purposes that CMS can justify.	Adopted June 2002
204	Provide comprehensive training, as opposed to broad based generalized training, for carrier and fiscal intermediary telephone customer service representatives (CSRs) so that CSRs are more knowledgeable in specific areas, and can improve their level of consistency in providing answers. Consider the merits of credentialing some or all of the contractors' CSRs in order to ensure that issue experts can directly respond to specific provider inquiries.	Adopted June 2002
205 *	Convene relevant stakeholders to work with CMS to: • reconcile conflicts in regulations and/or guidance that prevent clear delineation as to which entity (the SNF or the hospice) is required to be the lead in providing required end-of life care to SNF residents once they elect their hospice benefit; • revise guidance and procedures to recognize end-of-life care in the context of the survey protocol and the nursing facility's operations under each individual agreement with hospice; and • define the precise, unambiguously stated conditions under which, terminally ill beneficiaries who are residents of SNFs/NFs, may access their statutorily entitled hospice benefit. Incorporate these revisions and criteria-based conditions into the SOM, as part of interpretive guidance for surveyors of hospice and SNF/NF providers, at Task 6, K., at other relevant sections of the Guidance to Surveyors, as well as into relevant Program Integrity Instructions that ultimately affect the ability of hospice and SNFs/NFs to provide these services. Reconvene all relevant stakeholders to determine if more	Adopted June 2002

No.	Adopted Recommendation	Committee Action
	structural changes are needed, based on the degree of success achieved by the newly issued guidance. If necessary, revise and incorporate changes (including criteria developed from above) to the CMS COPs for both hospice and SNFs/NFs in order to assure that beneficiaries may access their statutorily entitled benefits and the appropriate entity can be held accountable. Implement final rule and provide training to both hospice and SNF/NF surveyors and providers.	
206	Issue a revised policy declaring that due to the national nursing shortage, we are in a period of "extraordinary circumstances." Due to this problem, contracting for nursing services for continuous care is allowed. The statement should restate the responsibility of hospice when contracting for services, located in 42 CFR § 418.80.	Adopted June 2002
207	Convene relevant stakeholders to work with CMS to revise the threshold definition of "harm" as applied in the SNF/NF enforcement process, and operationalize item-specific criteria for decision making at each relevant survey requirement. Publish the results of this collaboration in a NPRM and revise relevant regulations, as needed. Implement the final rule; develop guidance for survey and enforcement; provide training to surveyors and providers; and require CMS to monitor its application by surveyors.	Adopted June 2002
208	Convene relevant stakeholders to work with CMS to amend the threshold definition of "repeat deficiency" as applied in the SNF/NF enforcement process; insure that the more serious remedy associated with a repeat deficiency can only be applied in the presence of a repeat occurrence of the same problem, and/or a repeat deficiency of the same subordinate requirement within the larger regulatory group. (For example, under the larger regulatory grouping, "Quality of Care," there might be a citation related to wound care on one survey, and a citation related to personal grooming, found on a subsequent survey. For purposes of the Advisory Committee's recommendation, the latter citation would not constitute a "repeat deficiency" of wound care, and hence the more serious penalty would not be imposed.) Issue a NPRM adding the revised definition from above at 42 CFR § 488.401 and related requirements, as needed; publish a final rule; develop and issue corresponding instructional guidance in SOM Chapter, 7, Section 7516, and (C)(3). Provide training to surveyors and providers; require CMS to monitor its application by surveyors.	Adopted June 2002
209	Convene relevant stakeholders to define and clarify the criteria for when a determination of a "quality of care" deficiency rises to the threshold level of "abuse and neglect." Publish a NPRM incorporating these criteria and related requirements; amend the SOM Guidance to include and implement these new definitions; and provide training to ROs, States, and providers.	Adopted June 2002
210	Issue a NPRM modifying the regulation at 42 CFR § 488.331, and elsewhere as necessary, to require (as opposed to making optional): • SAs and CMS ROs to implement Informal Dispute Resolution (IDR) programs that afford facilities an opportunity to request and receive a face-to-face review for those deficiencies they feel cannot be adequately addressed through telephone or written communication. (NB: Until such time as a regulation can be promulgated, issue instructions encouraging SAs and the CMS ROs to offer face-face opportunities to the maximum extent possible.) • IDRs, as stipulated above, be incorporated as a required step in all provider appeal procedures related to survey and certification (see also recommendation #211), including use of IDR in instances of a surveyor's failure to follow required Federal procedures. • IDRs be conducted in a timely fashion (see also recommendation #218), and notice be given to the facility of its opportunity to request IDR. • That IDR programs be conducted through an independent third party who is not connected to the SA, RO or the facility. Implement the final rule; issue revised instructions and guidance; and provide training to surveyors, States and providers.	Adopted June 2002
211	Issue a NPRM modifying the regulation at 42 CFR § 498 to permit providers the opportunity to (1) appeal noncompliance whether or not a remedy is actually imposed; (2) to challenge severity and scope determinations; and (3) to challenge choice of	Adopted June 2002

No.	Adopted Recommendation	Committee Action
	remedies recommended or imposed, including modification to related citations. Implement the final rule; issue instructional guidance; and provide training to ROs, States and providers.	
212	Strengthen the quality of SOM communications (e.g., survey procedures, interpretive guidance, written instructions, etc) written for the primary audience of SAs and surveyors, by infusing it with a more positive, less provider-adversarial tone and stance. Include specific instructions and guidance that suggest or favor increased communication between surveyors and providers, including allowing surveyors to exchange information with providers on best or innovative practices. Design training programs for surveyors and providers that implement these types of less adversarial, more collegial types of changes.	Adopted June 2002
213 *	Issue a NPRM that would allow CMS to grant waivers to SSAs to test and implement alternatives to the survey and enforcement process currently required to assess Federal quality of care and resident outcome requirements. Implement a final rule, develop criteria and guidance to states in making application to CMS for such waivers; issue guidance for survey and enforcement purposes; provide training to States, surveyors and providers; evaluate the efficacy of waivers that have been granted, in relation to the efficacy of CMS's current survey process in terms of overall improvement to quality and care and resident outcomes.	Adopted June 2002
214 *	Issue a NPRM modifying the enforcement regulation in order to defer the ability of the SAs to suspend a facility's nurse aide training programs pending the final results of an appeal; implement the final rule issue required instructional guidance; and provide training to ROs, States and providers.	Adopted June 2002
215	Modify existing regulations in order to allow providers the option to utilize electronic images, transmittals and automated vendor file exchange data receipts as evidence to support costs claimed for reimbursement in place of the currently required "hard copy" originals of such evidence.	Adopted June 2002
216	Convene relevant stakeholders to modify and operationalize the definition of "substandard quality of care" and defining the exclusive set of the subordinate requirements/survey tags whose citation can constitute the threshold determination of substandard quality of care (i.e., only those requirements that deal with the provision and quality of care, and/or to the training of nurse aides, but NOT to the citation of other SNF/NF requirements, e.g., having sufficient closet space, etc.). Issue a NPRM to this effect; publish and implement a final rule; issue revised instructional guidance; provide training to the surveyors and providers.	Adopted June 2002
217	Issue a NPRM modifying 42 CFR § 488.318(b)(2) so that when inadequate survey performance (e.g., "failure to cite only valid deficiencies, failure to use Federal standards, protocols, and the forms, methods, procedures, policies and systems as specified by [CMS]…") is demonstrated/established to have contributed to the citation of a deficiency, that the CMS RO or SA must conduct follow-up (including onsite investigation, if necessary) to validate the presence of the deficiency, if a corresponding remedy is to be applied. Implement the final rule; and require CMS to monitor its application.	Adopted June 2002
218	Issue a NPRM modifying the regulation at 42 CFR § 488.331 to include criteria for "timeliness" (so that it applies to timely transmission of both the CMS Form 2567 [Statement of Deficiencies] and the notice to the facility of its opportunity to request an IDR.) Until such time as a regulation can be promulgated, issue instructional guidance to State and Federal survey agencies establishing preliminary criteria for timely response to IDR requests. Implement final regulation; and provide guidance and training to ROs, States and providers.	Adopted June 2002
219	Develop a database for practitioners, patients and caregivers to help prevent known potential adverse interactions between and among drugs, foods and dietary supplements. Once a patient, caregiver, or any medical professional enters a patient's complete drug regimen into this database, the program would alert the patient to the level of risk and/or benefit of any known potential interactions. (For this recommendation, the term "drug" includes prescription and over-the-counter medications, and the term "dietary	Adopted June 2002; Re-Adopted September 2002

No.	Adopted Recommendation	Committee Action
	supplements" include but are not exclusive to herbal and nutritional supplements. An existing example can be found on the web at www.aidsmeds.com.)	
220	Publicize the user-friendly, drug-food-dietary supplement interactions database to mitigate any increases in health care costs due to adverse events. (For this recommendation, the term "drug" includes prescription and over-the-counter medications, and the term "dietary supplements" include but are not exclusive to herbal and nutritional supplements.)	Adopted June 2002; Re-Adopted September 2002
221	Immediately launch an educational and information campaign to educate patients and all healthcare professionals about the MedWatch system (an adverse event reporting system operated by the FDA) to increase the reporting of adverse events until an improved, automatic information technology system is established.	Adopted June 2002
222	Create a FDA/HHS Working Group of all affected stakeholders to look at the current IT systems that have automatic reporting for adverse events, adverse drug reactions and medical errors; study the feasibility of developing a National Automatic System. (An existing example can be found on the web at www.PRHI.org.)	Adopted June 2002
223	Use the Centers for Education and Research on Therapeutics (CERTs) for collection of adverse event information from all healthcare providers, both public and private. Use CERTs to develop a central repository of drug adverse event reports from all healthcare providers. CERTs should conduct Phase IV Trials when, in consultation with the FDA, it has been decided that a Phase IV Trial may be necessary to answer new questions that arise from newly reported adverse events.	Adopted June 2002
224	Design and implement, as soon as possible, a demonstration project to deploy Medicare smart cards to selected beneficiaries. Include a chip on the card that would contain basic beneficiary data in a write-protected form so it could not be altered by an unauthorized user. Ensure that the smart card can be used by providers, beneficiaries, and the industry to store information. (Note: the long-term goal of this initiative is to create an electronic medical record.)[42]	Adopted September 2002
225	Establish a multidisciplinary panel to evaluate open architecture applications for use with a Medicare smart card. Direct the panel to make recommendations to approve or reject proposed open architecture applications for the Medicare smart card. Give special attention to privacy concerns. Seek technical assistance from the OIG to prevent fraud and abuse. ("Open architecture" provides a platform on which users can layer software and data. Outside groups would be encouraged to develop ways to expand the card's use beyond simple identification with data stores and interfacing applications. Additional issues for consideration upon deployment of a smart card include: • determining whether all applications developed by the health care community should be funneled to the panel for consideration before being implemented or whether this panel would support a community model in which various entities would develop software applications themselves on an ongoing basis, producing creative mechanisms and seeking industry-wide standards, • acknowledging that the technological capacity of smart cards may require some organization to set parameters on the use of the card and the types of software that would be permitted for inclusion on the card, and • developing a formal public/private partnership to support private sector innovation for a government sponsored product and reconcile any issues that arise from this partnership.[43]	Adopted September 2002
226 *	Use the Medicare smart card as a tool for integrating medical information across the continuum of care over the long term. For example, allow for the integration of data	Adopted September 2002

[42] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

[43] The highlighted text reflects a change to the Committee's previously adopted recommendation. This revised text is contained in the Committee's Discussion Agenda for the November 21, 2002 Meeting.

No.	Adopted Recommendation	Committee Action
	from future electronic standard assessment instruments, enrollment forms, and medication administration records into smart card technology.	
227	Issue written guidance to surveyors stating that 42 CFR § 418.88b, which requires as a condition of participation for hospice providers that dietary counseling by qualified individuals is available, does not preclude nurses or other qualified health professionals from providing dietary counseling. (Could be implemented with a memorandum.)	Adopted September 2002
228	Revise the Hospice COPs to provide an exception to the twenty-four (24) hour nursing services standard in the hospice COPs when respite care is provided (without undermining basic health and safety standards for hospice patients.).	Adopted September 2002
229	Collaborate with States to ensure that State Plan Amendments and State waiver requests (for example, 1115 waivers) are approved in a manner that is timely, significantly decreases unnecessary documentation, and fosters State program innovation. CMS should adopt a reasonable, workable, preset schedule for completing State requests for plan amendment approvals and waivers. (This would enable States to promptly provide a continuum of services to all beneficiaries in the least restrictive setting, regardless of whether those beneficiaries have disabilities.)	Adopted September 2002 with dissents from Mr. Bloom, Ms. Osborne Shafer and Ms. Pattee
230	Issue immediately a written statement that "Medicare hospice providers must recognize the individual's right to self-determination at the end of life and hospice staff should be prepared to provide CPR for hospice patients that request to be resuscitated or do not have a DNR or advance directive."	Adopted September 2002
231	Recognize the significant impact of coordination of benefits on the quality of care provided to individuals who are dually eligible to participate in the Medicare & Medicaid programs. Establish an advisory group of key stakeholders including representatives from CMS, FIs, carriers, providers, State Medicaid directors, and beneficiaries to determine a process to significantly improve COB for this group and to reinforce the CMS ROs' authority to deal with regional and other specific concerns that arise. • The advisory group will be established no later than March 31, 2003 and it will have a six-month time frame to submit recommendations. • The advisory group will be charged with finding national solutions to dual-eligible coordination issues including, but not limited to: timeliness of decision making, accountability of fiscal intermediaries, quality assurance, and program issues that impede desired outcomes. The advisory group will focus on formulating best practice guidelines to aid in the decision making process at the fiscal intermediary level, creating clear timeframes for decisions on coverage, and assisting with decision-making guidelines. • Recommendations from this advisory group will be relayed to FIs and providers in the form of education about determination of coverage, with the goal of removing obstacles to determination of coverage and quality care.[44]	Adopted September 2002
232	Require that Medicare FIs and carriers pay claims in review for longer than 45 days for unresolved situations in which Medicaid or Medicare may be obligated to pay. Develop systems for Medicare to ensure the timely recoupment of payments that are determined to be the responsibility of Medicaid upon final review.	Adopted September 2002
233	Develop an online, real-time claims adjudication system for Medicare that gives payors information relating to coverage, reimbursement, and COB at the point of service whenever possible.	Adopted September 2002
234	Promote the broadest dissemination of the "Best Pharmaceuticals for Children Act" mandate for a 1-800-Toll-Free number for reporting of adverse drug events when promulgating a final rule under P.L. 107-109. The toll-free number should appear in an easily identifiable location. The Committee also recommends that manufacturers voluntarily begin placing this number on unit of use or ready-to-dispense prescription	Adopted September 2002

[44] The Committee is most concerned that the Department set a date certain to achieve this recommendation, not necessarily setting the certain date specified by the text in this recommendation.

No.	Adopted Recommendation	Committee Action
	packages to minimize the impact on pharmacy.	
235	Adopt safe labeling practices for all FDA-regulated products to improve patient safety and decrease avoidable adverse drug events. For example, adopt labeling standards with respect to label format, information placement, information presentation and standardized definitions (and measurements.)	Adopted September 2002
236*	Issue a Memorandum of Understanding (MOU) between the FDA and CMS that considers the interest of stakeholders and defines the process the two agencies will employ to permit the exchange of information and support collaboration relative to their respective reviews of innovative medical device technologies while maintaining the confidentiality of trade secrets and other proprietary data. Propose regulations to achieve specific elements of this recommendation, as needed.	Adopted September 2002
237	Formally promote and encourage the implementation of processes to expedite FDA notification of CMS when an Investigational Device Exemption (IDE) designation, i.e., Category A or B, has been granted, and ensure complete and timely CMS transmittal of such notification to local carriers and fiscal intermediaries.	Adopted September 2002
238*	Shift from doing name safety testing, in most cases, to reviewing data from sponsors who follow protocols designed to evaluate the potential for look-alike and sound-alike errors with generic and proprietary names prior to approval of FDA-regulated drugs. Use information gathered from the name safety research to improve patient safety by minimizing post-marketing medication errors linked to name similarity and practitioner confusion.	Adopted September 2002
239	Encourage all relevant parties (FDA, other HHS agencies, consumer groups, industry, pharmacy groups) to issue educational materials on the reporting of adverse events targeted to the patient and health care provider audiences. Such materials should be designed to encourage reporting of appropriate adverse events by patients and health care providers.	Adopted September 2002
240*	Issue regulations that would require all appropriate FDA-regulated products to be packaged to take full advantage of appropriate administration and patient identification technologies, and consequently, to prevent medical errors.	Adopted September 2002
241*	Establish a process, with input from affected stakeholders, to enable early coordination between FDA and CMS and, when appropriate, permit parallel reviews, during the design of clinical trials for medical device technologies thereby promoting more timely patient access to innovative therapies without slowing down the FDA approval process.	Adopted September 2002
242*	Announce publicly and promote through outreach to stakeholders the process (e.g., relevant structures and time frames) for the implementation of recommendations relating to FDA/CMS coordination related to new medical device technologies.	Adopted September 2002
243	To facilitate timely release of new medical device technologies and to enable CMS to support the processes for enhanced FDA/CMS coordination on new medical device technology issues: • Encourage CMS to issue guidance in consultation with stakeholders on Medicare coverage standards (guidance is not legally binding); • Recognize the importance of and support the maintenance of LMRPs; • Support the timely issuance of HCPCS consistent with the Advisory Committee's recommendation to adopt a defined schedule for issuance of proposed and final modifications, additions, and deletions to the transaction standards; • Eliminate the requirement to submit six months of marketing data (post-FDA approval) prior to the acceptance of the Health Common Procedure Coding System (HCPCS) application; • Improve the effectiveness and efficiency of the national coverage decision process by promoting CMS consideration of reliable data from outside sources in the coverage and payment review processes; • For decisions involving national coverage for new technologies without a referral for technology assessment or to the Medicare Coverage Advisory Committee (MCAC), direct CMS to establish and maintain a six-month	Adopted September 2002 with dissents from Ms. Ryan and Mr. Bloom

No.	Adopted Recommendation	Committee Action
	timeframe for issuing decisions. If a referral is required, establish and maintain a 12-month timeframe for decisions; • Allocate adequate CMS staff and resources to meet expedited time frames for national coverage decisions.	
244	Determine processes for timely review of FDA-regulated combination products by dedicating staff to the development of appropriate policies or establishing a new Office of Combination Products.	Adopted September 2002
245	Encourage electronic submission of applications to market new FDA-regulated products, including all relevant information that can be furnished electronically.	Adopted September 2002
246*	Add information on clinical trials for IDEs to the clinical trial database for drugs and biologics. Seek stakeholder input in this process, while ensuring confidentiality of proprietary information. Establish, as a priority, the implementation of this database for all FDA-regulated products.	Adopted September 2002
247	Develop separate MedWatch forms for pharmaceutical products and medical devices.	Adopted September 2002
248	Support government-wide efforts to simplify and harmonize requirements related to human subject research; maintain strong human subject protections and balance individual medical privacy rights with the societal health benefit that results from effective medical research.	Adopted September 2002
249	Support the activities of the HHS Working Group to respond to the National Bioethics Advisory Commission report, *Ethical and Policy Issues in Research Involving Human Participants*.	Adopted September 2002
250	Issue proposed, interim final, and final CMS regulations on one business day of every month, unless another date is necessary to comply with the law or is contrary to public interest. Issue interpretive guidance on a biweekly schedule that coincides with the promulgation of all related final regulations.	Adopted September 2002
251	Revise the rulemaking process to: Establish an effective, front-end system in CMS that allows for stakeholder (provider, supplier, plan, consumer) participation and feedback among and between stakeholders and affected agencies on issues such as cost estimates and underlying assumptions, implementation issues and value to the consumer. • Include costs for implementation and compliance. • Evaluate costs and processes one year after publication of the final rule for selected high cost/high burden regulations. • Coordinate issuance of new CMS regulations relating to a category of providers, suppliers or health plans based on a (marketplace) analysis of the collective impact of regulatory changes on that category of provider, supplier or health plan. • Simultaneously promulgate regulations that are directly related to each other or otherwise impact on each other (should be the usual practice.) • Consider greater use of the Advance NPRM to gather early feedback.	Adopted September 2002 with dissent from Dr. Olsen.
252	Ensure the uniform application and implementation of policies, rules and guidance across CMS ROs and the CMS CO: • Institute training programs that involve all stakeholders- the affected entity, regional and central office staff and any outside Department/Agency contractors. • Ensure common understanding by all affected parties of rules and guidance to assure that surveyors and oversight agencies' guidance and review do not run counter to that of the issuing agency or the State.	Adopted September 2002
253	Examine ways to expedite approval timelines and procedures to get products, services, processes or benefits to market faster to respond to evolving consumer needs.	Adopted September 2002
254 *	Implement a process to continually review and update current regulations against statutes, policies and guidance to ensure relevancy and consider either an automatic review or sun setting process for particular regulations or categories of regulations.	Adopted September 2002
255	Examine the processes and procedures that ensure the Department's agencies use the	Adopted September

No.	Adopted Recommendation	Committee Action
	most current and reliable data in the rulemaking and interpretive guidance processes, including performance standards or guarantees with contracting entities.	2002

APPENDIX C

UNFINISHED COMMITTEE BUSINESS

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The Committee was unable to address all of the issues raised during its deliberations; the Committee's scope of work was broad and the timeframe in which the Committee was charged to complete its work was narrow. Following is a catalogue of the proposed recommendations that were either formally discussed or put forth for Committee consideration, but were not brought to closure. Inclusion of proposed recommendations in this list does not imply Committee endorsement, nor does it imply rejection. [Those marked by an asterisk [*] may require legislative action.]

1*	Expand Medicare waiver authority, selectively, beyond the current limited authority to waive coverage, and reimbursement, to accomplish several high priority goals of the Committee, including but not limited to: • Demonstrations of unified service delivery to Medicaid/Medicare dual eligibles. • Testing of regulations in limited geographic areas before requiring national implementation. • Allowing greater flexibility to test the efficacy of alternative State survey protocols for skilled nursing facilities/nursing facilities, as per recommendation #213 (Multiple Reviews); • Enabling providers to access government data for the purpose of improving quality of care, while retaining system security and patient privacy protections. [NOTE: this recommendation also addresses issues identified in the following recommendation, which was also proposed but not voted upon: Amend the Medicare+Choice statute and general provisions of the Medicare statute, respectively, to create explicit new Medicare waiver authority for voluntary programs that coordinate or integrate Medicare & Medicaid services. Use language that goes beyond existing authority by explicitly including many programmatic elements in the waiver authority. The waiver should include the beneficiary's right to an expedited appeal and the right not to have services terminated pending appeal. (Permit States to coordinate benefits under a Medicaid plan under Title XIX with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services.)]
2*	Medicare should consider covering long-term care and prescription drugs for the elderly. It is illogical for the Federal "Health Insurance for the Aged" program not to cover long-term care and prescriptions for the aged, yet the States are expected to cover these drugs.
3*	If Medicare does not cover long-term care and prescriptions for the elderly and Medicaid 1115 waivers continue to exist, the HHS policy of not recognizing savings in Medicare when determining budget neutrality should be reversed. The States bear the enormous cost of prescription drugs and long-term care, which saves Medicare greatly, yet States are not allowed to recognize the Medicare savings when defending waivers.
4*	Fiscal intermediaries and carriers should apply the definition of terminal illness in a common sense manner recognizing that the "six months" language is an expected average only. A person certified as expected to die within six months may survive longer but continue to be terminally ill and in need of hospice.
5*	Avoid forcing a physician to guess the course of illness for an individual by amending the Federal regulation to reflect Michigan law PA 239, which was passed in 2002: "The certification must specify that the individual has a limited life expectancy due to advanced illness." Advanced illness "means a medical or surgical condition with significant functional impairment that is not reversible by curative therapies and that is anticipated to progress toward death despite attempts at curative therapies or modulation, the time course of which may or may not be determinable through reasonable medical prognostication."
6*	Amend Title XVIII, Section 1859(d) as indicated by underlined text, by waiving Medicare + Choice statute requirements to allow for integration of services. (Permit States to enhance the

	coordination and integration of services and administration provided under this title with services provided under Title XIX.) [See original recommendation submitted June 2002 for reference to underlined statutory text.]
7*	Create a new Section 1897 as indicated by underlined text, by waiving Medicare requirements to allow for integration of services. (Permit States to enhance the coordination and integration of services and administration provided under this title with services provided under Title XIX.) [See original recommendation submitted June 2002 for reference to underlined statutory text.]
8*	Amend section 1915(a) of the Medicaid statute to add sub-Section 3 allowing streamlined contracting processes for dual eligible programs. (A case management /coordinated care option for beneficiaries to choose.) [See original recommendation submitted June 2002 for reference to statutory language sub-Section 3.]
9*	CMS should require that all Medicare mental health beneficiaries have developed by a case manager or mental health provider in conjunction with the recipient, a case management plan that includes: Medicaid treatment options (if eligible), community-based provider options, and a person-centered plan.
10*	Reimburse services of medical interpreters provided to individuals with limited English proficiency ordered by a provider or requested by a patient.
11	Defer the effective date for compliance with new [CLIA] requirements as long as possible after the date of publication to allow laboratories time to implement the new requirements.
12	Implement MedPAC's recommendation that CMS "move to a standard nationwide system of claims processing and eliminate local description of policy and regulation."
13	A substantive change to the text that would consolidate and clarify the intent behind four of the Committee's previously adopted recommendations – The text of the proposed new recommendation would read: Issue a NPRM revising the definition of deficiency at 42 CFR § 488.301 such that a deficiency cannot be cited in the absence of a surveyor's having implemented an organized methodology for determining compliance, including but not limited to: systematic investigation, information analysis, validation, and determination of facility response and responsibility in identifying a potential problem and acting to prevent it. Publish the final rule and instructional guidance, and provide training to surveyors and providers. Follow-up and monitor consistency in application.
14	A substantive change to the text that would consolidate and clarify the intent behind two of the Committee's previously adopted recommendations – the text of the proposed new recommendation would read: "Revise and clarify surveyor guidance in Appendix Q, to clarify that a threshold determination of "immediate jeopardy" cannot be made until surveyors have implemented a two-step process consisting of: • first establishing the fact of regulatory noncompliance, and then • determining whether the established noncompliance meets the definition of "immediate jeopardy," based on the seriousness of the consequence or potential consequence of the facility failure to meet the requirements. • issue and implement revised guidance; provided training to regulators and providers."
15	Modify the regulation at 42 CFR § 489.18(d) to allow new owners/sponsors, in a bona fide, "arms length" transaction, the opportunity to take corrective actions and demonstrate compliance absent the burden of all enforcement actions or remedies imposed under prior management [under HIPAA regulation]. • Immediate: CMS should issue a notice of proposed rulemaking to allow new owners/sponsors, in a bona fide, "arms length" transaction, the opportunity to take corrective actions and demonstrate compliance absent the burden of all enforcement actions or remedies imposed under prior management. • Long-term: Implement a final regulation; provide guidance and training to regional offices, States, and providers.
16	Amend the answer to State Operations Manual question 9Q to read, "No, a visit to determine if immediate jeopardy is abated will not count as one of the two revisits." [i.e., delete the 2nd and 3rd full sentences.]

	• Immediate: Amendment of CMS Policy Memorandum S & C 01-23, August 15, 2001, Response to Questions about Verification Policy (S&C01-10) question and answer at 9Q. • Intermediate: Amendment to SOM Chapter 7 to clarify that a visit to determine abatement of Immediate Jeopardy will not be included in the revisit count. Provision of guidance and training to regulators and providers.
17	Promulgate a regulation that would permit facilities to train non-nursing personnel to provide specialized or "single-task" training, such as assistance with eating, by personnel other than nurse aides. These individuals would augment but not replace existing staff, and would have to demonstrate competency, but would not have to complete the full nurse aide training and competency evaluation. • Immediate: CMS should propose a Notice of Proposed Rulemaking open to public comment. • Long-term: Implement a final rule; provide training to regulators and providers. • Permit deemed status for alternative survey process.
18	Establish an improved system for timely and accurate identification of dual-eligibles, including the appointment of a CMS team (Medicare/Medicaid) to devise said system with a report containing recommendations due by December 31, 2002. Implement a pilot no later than June 1, 2003.
19	CMS should work with the NAIC to ensure that appropriate financial solvency standards are in place for providers and other organizations that assume risk.
20	Within statutory parameters, CMS should accept alternative mechanisms, such as on-line Medicaid enrollment applications, and allow those mechanisms to be used as evidence in case of potential fraud investigations.
21	Make HIPAA consent optional for all covered entities [under HIPAA regulation]. [45]
22	Require authorization for any non-face-to-face marketing [under HIPAA regulation].
23	Resolve the organized health care arrangement [under HIPAA regulation].
24	Permit disclosure for another covered entity's treatment, payment, and quality, competency and oversight health care operations [under HIPAA regulation].
25	Clarify that "minimum necessary" does not apply to use for treatment [under HIPAA regulation].
26	Exempt specified treatment-like health care operations from the "minimum necessary" limitation [under HIPAA regulation].
27	Clarify that covered entities may rely on protected health information requests from plan sponsors qualified to do plan administration functions to be for the "minimum necessary" [under HIPAA regulation].
28	Make an exception for medical information internal use from "minimum necessary" by removing the references to "use" and "using" in 45 CFR § 164.502(b), specifying in Section 164.502(b)(2) that "minimum necessary" does not apply to use of protected health information and deleting Section 164.514(d)(2) [under HIPAA regulation.]
29	Make an exception from disclosure accounting requirements for two forms of authorized disclosures [under HIPAA regulation]: • Disclosures pursuant to an authorization that an individual initiates and • Disclosures pursuant to an authorization that a covered entity requests, and that specifically identifies each entity permitted to disclose the medical information, each entity to be permitted to receive and use the information, and the dates or time frame during which the disclosures may be made.
30	Make an exception from disclosure accounting the disclosures by a group health plan to sponsors of enrollees' protected health information for the plan sponsor to perform plan administration functions [under HIPAA regulation.]
31	Adopt a "Compliance Certification" option for non-covered entity business associates [under

[45] Items 21 – 31 and 54 – 74, as enumerated, all deal with the HIPAA Privacy Rule. This subset of unfinished business items was formulated with public input that was received prior to issuance of both the March 27, 2002 NPRM and the August 14, 2002 Final Rule, and hence these proposals may not reflect these changes.

	HIPAA regulation].
32	Automate standards and code set updates (45 CFR § 160.104, Part 162.)
33	Long-term care and new technology codes (45 CFR § 162.1000 et seq.). The affected industry segments need to develop, through an ANSI accredited mechanism or directly with HHS, code sets applicable to their activities for use in standard transactions. At least the affected industry segments should provide and HHS should adopt "translation maps" that convert current local codes to the CPT-4, ICD-9-CM, and HCPCS code sets that have been adopted for the current standard transactions.
34	Using OMB A21 guidelines, HHS should make the indirect cost recovery proposal review process a true audit review conducted by audit professionals in the Office of the Inspector General. The OIG should employ a process similar to audits of Medicare cost reports or to IRS corporate tax return audits. Risk-based parameters, such as scale, departure from averages, large changes from submission to submission, etc., would determine whether audits were conducted on submitted proposals. Predictive indicators to determine bases for reviews could be developed by a joint University-HHS task force. Rates would be based upon the submitted proposals or proposals adjusted by specific audit disallowances subject to a defined and timely appeals process. Rates could be set for multiple years, as is the current case. Administration of the process would be strictly monitored from region to region for consistency in the application of rules and standards. In cases where audits discovered deliberate misrepresentation or egregious flouting of the rules of proposal preparation, offending institutions would be required to pay appropriate penalties, including the government's cost of conducting reviews. Overall, the objective would be to use sampling and audit methodologies to greatly reduce the number and frequency of negotiations and the unfair inconsistencies in the current process.
35	Planning should begin for a demonstration project to test ways to efficiently allow a provider to go to a website, enter a procedure and diagnosis, and find out if the service is likely to be covered or non-covered. CMS would create a full loaded "coverage database" accessible to the public via the cms.hhs.gov website, starting with all LMRPs and eventually containing all national coverage decisions, national and local bulletin articles on coverage topics, and all national and local FAQs on coverage topics. This database will be a single site where the public can search for keywords in all of these sources. In the future this system, could be modified to allow providers/ beneficiaries to determine in advance of receiving a service whether the service is likely to be covered or noncovered by Medicare.
36*	CMS should develop an A-19 to require: carriers to develop word-for-word identical carrier LMRPs; FIs to develop word-for-word identical FI LMRPs; and DMERCs to develop word-for-word identical DMERC LMRPs.
37	Currently CMS' Progressive Corrective Action initiative directs contractors to address providers with moderate error rates using the corrective actions of education plus prepayment review. CMS should revise this approach such that providers with moderate error rates are subjected to education only. If the provider improves, no further corrective action is taken. If the provider fails to correct the billing behavior, the contractor would initiate prepayment review.
38	CMS should double its local provider education and training budget for 2003.
39	CMS should conduct an annual survey/measurement of providers' satisfaction with the customer service and education they receive from Medicare.
40	CMS should encourage contractors to tell providers on a provider-specific review what their error rate is on monthly basis (now it is quarterly.)
41	CMS should develop a mechanism for contractors to let providers see their return/reject rates via a web-based application.
42	CMS will allow contractors to provide "comparative billing reports" (showing utilization rates) to providers and specialty societies upon request.
43	CMS should develop a national provider bulletin with local customization. CMS will hire professional editors and authors to develop articles explaining complex matters in plain language. These bulletins will be distributed via a national email listserve system. Providers with no Internet access can subscribe to the fax version of the newsletter. These articles should be archived in the "coverage database" (described above) for future online searches.
44	CMS will revise the LMRP format instruction removing the requirement that contractors include a description of national coverage policy. Instead, contractors will be required to list the citation for the national coverage policy.

45	CMS should develop a method for evaluating the accuracy and completeness of responses given by contractors to written and phone inquiries from providers and beneficiaries.
46	Each year, CMS should identify the "top 5 education topics" – the 5 coverage/coding/billing issues that are most contributing to the Medicare "error rate." CMS and its contractors should put extra emphasis on these topics during the year.
47	CMS should instruct contractors to be more specific when requesting additional documentation from providers.
48	CMS will remind contractors of existing requirement that they have a focal point for answering coding questions. CMS should direct contractors to publicize on the web the name, telephone number, and e-mail address of a specific individual serving as a point of contact so that providers can submit coding questions to the right place. Similarly, CMS should develop a new requirement that contractors have a focal point for answering coverage questions, and direct them to publicize this on the web to help providers find the right place.
49	CMS should monitor the accuracy and completeness of responses given by all contractor staff in response to coverage and coding questions (including, all call center staff, provider relations staff, written inquiry staff, PET staff, medical review staff, etc. The process for scoring accuracy of coverage/coding questions should involve clinicians and coding professionals.
50*	CMS should pilot test at a DMERC, monitor results, and expand if appropriate the idea of assigning a single customer service representative to each provider.
51	Administer the procedure that Medicare uses to medically review claims consistently and in a manner that decrease the burden and cost to Medicare providers: • Allow at least six (6) weeks for providers to submit medical records for review and require contractors to contact affected providers prior to any denial to allow the provider the opportunity to respond; • Provide an expedited appeals process and require recovery after the appeals process is exhausted; • Establish uniform performance standards for contractors with both positive and negative incentives and provide such for contractors and providers; • Establish a CMS oversight board with representatives from all segments of the health care industry to oversee reform; and • Establish performance standards for FFS contractors similar to those required by private sector employers for their vendors.
52	The Secretary should support the activities of the NIH Regulatory Burden Advisory Group and consider all recommendations as appropriate.
53	Urge Congress to appropriate the authorized funding for HIPAA transactions rule implementation.
54	Adopt the HIPAA Privacy NPRM' provision that the criteria to support a waiver of authorization be reduced from eight criteria to three. The U.S. Department of Health and Human Services (HHS) should retain the three proposed provisions: • the use or disclosure of protected health information (PHI) involves no more than a minimal risk to the privacy of individuals; and • the research could not practicably be conducted without the waiver or alteration; and • the research could not practicably be conducted without access to and use of PHI. HHS also requires assessment of three factors as part of the waiver criterion for assessment of minimal privacy risk, including: • plans to protect identifiers from improper use and disclosure, • plans to destroy the identifiers at the earliest opportunity, and • adequate written assurances against redisclosure.
55	HHS should require that, to provide additional guidance to address the concerns and confusion about HIPAA Privacy research provisions, it should consult with experts on human research protections at the FDA.
56	Adopt the HIPAA Privacy NPRM provision of a single set of requirements to apply to all types of authorizations, including those for uses and disclosures of PHI created for research that includes treatment of the individual. This will eliminate the specific provisions of § 164.508(f) for authorizations for uses and disclosures of PHI for research that includes treatment.

57	Adopt the HIPAA Privacy NPRM provision that an authorization for the use or disclosure of PHI for research can be combined with any other legal permission related to the research study, including another authorization or consent to participate in the research. This applies to research with and without treatment.
58	Adopt the HIPAA Privacy NPRM provision that the statement "the termination of the research project, or the extinguishing of the need to review, analyze and consider the data generated by a research project, whichever is later" or similar language is sufficient to meet this requirement for an expiration date or event where the authorization is for a use or disclosure of PHI for research.
59	Adopt the HIPAA Privacy NPRM provision that the statement "none" or similar language is sufficient to meet this provision if the authorization is for a covered entity to use or disclose PHI for the creation or maintenance of a research database or repository, which are often retained indefinitely.
60	Recommend that HHS allow a single form to authorize release of data to a database or repository and subsequent use and disclosure of these data for specific purposes.
61	Suggest that HHS amend regulations to allow for continued use and disclosure of data for research by amending authorization to inform individual that, upon revocation, data gathered in the interim may be used for specific purposes, such as validation of results.
62	Adopt the NPRM proposal to permit a covered entity to use or disclose for a specific research study PHI that is created or received either before or after the compliance date, if the covered entity has obtained, prior to the compliance date, an authorization or other express legal permission from an individual to use or disclose PHI for research study. Also, adopt the NPRM proposal to grandfather in research in which the individual has signed an informed consent to participate in the research study, or an IRB has waived informed consent for the research study in accordance with the Common Rule or FDA regulations.
63	Under HIPAA Privacy, HHS should "grandfather" in data in existing databases. These should apply to all databases, including those held by academic, institutional, nonprofit, and individual researchers, and those created without the requirement of informed consent or waiver. We urge HHS to provide for this continued use, which is recommended by several members of Congress.
64	Under HIPAA Privacy, HHS should not limit the de-identification of information to these two methods. (See issue 66 on limited data set.)[46]
65	Support the HIPAA Privacy NPRM provision that a code or other means of record identification (that would allow de-identified information to be re-identified by the covered entity) to be considered an identifier.
66	Adopt suggestions in the NPRM for HIPAA Privacy standards that a limited data set be created for specific purposes that would not contain the following direct identifiers: • name, • street address, • telephone and fax numbers, • e-mail address, • Social Security number, • certificate/license number, • vehicle identifiers and serial numbers, • URLs and IP addresses, and • full face photos and any other comparable images. HHS should provide an affirmative list of "direct identifiers" that will be stripped, and does not include any subjective or vague criteria such as "other unique identifying number, characteristic, or code" criterion included in the existing de-identification standard. This limited data set can be used only for research, public health and healthcare operations, but a limited data set is not required for these uses. HHS should allow certain identifying information to be retained according to specifications of other agencies, such as FDA's requirement for retention of Social

[46] Proposed recommendations regarding the Privacy Rule were formulated with public input that was received prior to issuance of both the March 2002 NPRM and the August 2002 Final Rule, and, hence, these proposals may not reflect those final changes.

	Security number and date of birth. HHS should clarify that device serial numbers can be included as they are vital for recalls and investigations and patient safety.
67	Under HIPAA Privacy, support the removal from the list of 18 items required for de-identification specific information, such as admission, discharge, and service dates; date of death; age (including age 90 or over); the dates on which the injury or illness was treated and patient released from hospital; date of birth; and five-digit zip code. The specific geographic information should allow for retention of five-digit zip code, city, county or neighborhood information (except for street address.)
68	Adopt the HIPAA Privacy NPRM provision to condition disclosure of limited data set to covered entity obtaining data use or similar agreement, in which recipient would agree to: • restrict the use of a limited data set to the specified purposes in the Privacy Rule, • limit who can use or receive the data, and • agree not to re-identify the data or contact the individuals. HHS should provide guidance on elements of the data use or similar agreement, which may include: • arrangements for removing all direct identifiers; • limitations on use of data set to research, public health, or health care operations; • limitations on access to personnel in these functions; • restriction of ability to identify, contact or attempt to identify or contact individuals; and • requirement for covered entity not to disclose a direct identifier or a key for assigning codes. HHS should obtain further suggestions on the parties to the agreement, and the attendant enforcement issues.
69	Adopt the HIPAA Privacy NPRM provision to exempt from the accounting for disclosures of PHI any disclosures made pursuant to an individual's authorization, including disclosures for research.
70	Under HIPAA Privacy, add to exemptions from accounting for disclosures any disclosures made for research pursuant to waiver, or for public health purposes. In lieu of accounting for individual disclosures, the covered entity can provide a list of all disclosures and contacts for disclosures made in previous six years and the possibility that the individual's PHI may have been disclosed. However, such a list may be optional as it may still be burdensome and not assist with privacy.
71	Adopt the HIPAA Privacy NPRM provision that covered entities may disclose PHI to persons subject to FDA jurisdiction with respect to FDA-regulated products or activities for which the persons have responsibility, provided that the disclosures are for the purposes of quality, safety or effectiveness of the FDA-regulated products or activities. Furthermore, HHS should expand this proposal to allow covered entities to disclose PHI to persons subject to other government requirements for these purposes, such as quality assessment activities by the Agency for Healthcare Research and Quality, and research oversight by the National Institutes of Health.
72	Under HIPAA Privacy, HHS should broaden the definition of entities (public or private, and non U.S. entities) who are involved in legitimate public health activities, such as tracking of emergence of disease that could result from bioterrorism, tracking of diseases for ongoing databases and quality improvement, post-marketing surveillance registries, tracking of devices or drugs/biologics for adverse events, FDA compliance by manufacturer for clinical trials, and research oversight. HHS could base the definition on the entity's functions to promote public health, rather than its nature as a public or U.S. entity.
73	Under HIPAA Privacy, HHS should allow for use of PHI for ongoing registry databases or repositories that are not subject to the requirements for authorization or waiver. Just as HHS allows for data to be disclosed to industry pursuant to FDA requirements, data should be allowed to be disclosed to academic institutions and other nonprofits or private researchers to construct valid registries for legitimate research purposes. Further, pre-research compilation activities must continue so that entities can build and maintain pre-research databases or tissue banks, before requiring authorization or waiver. HHS should amend the definition of health care operations to include this pre-research activity as well as the compilation of data into registries

	or repositories. Although some public comments suggested expanding the definition of health care operations to include some research activities, others expressed concern about expanding the definition of health care operations, asserting that this broad suggestion could undermine the acceptability of other changes to facilitate research. Alternatively, HHS could amend the research authorization exception for information compiled preparatory to research or compiled into valid public or private registries. HHS should identify safeguards to ensure appropriate protections of data privacy within registries and legitimate uses or compilations of data. Some examples include certification of nonpublic databases, and implementation of data use or similar agreements to protect data used for registries or repositories.
74	Under HIPAA Privacy, allow covered entities to review PHI in charts for clinical trial recruitment by considering this function to be included in health care operations. Alternatively, such discussions can be facilitated by limiting information disclosed to the minimum necessary and ensuring that the clinical investigator is subject to HIPAA. Or the investigator can obtain HIPAA authorization to seek enrollment, without specifying in the authorization the persons to whom the PHI would be disclosed, or the exact information to be disclosed, and then retain authorization requirements of duration and purpose, adding minimum necessary disclosure, and protect PHI from public disclosure or reuse.

APPENDIX D

CHARTER (AS AMENDED)

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PURPOSE

The Secretary's Advisory Committee on Regulatory Reform will provide findings and recommendations to the Secretary regarding potential regulatory changes that would enable HHS programs to reduce burdens and costs associated with Departmental regulations, while at the same time maintaining or enhancing effectiveness, efficiency, impact and accessibility.

AUTHORITY

This Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation of advisory Committees and implementing regulations (41 CFR 102-3.)

FUNCTIONS

The Secretary's Advisory Committee on Regulatory Reform shall advise and make recommendations related to health care delivery, operations, biomedical and health research as well as the development of pharmaceuticals and other medical products. The process of formulating recommendations would include regional public hearings and soliciting public comments regarding particular HHS regulations.

The Committee shall (a) review candidate regulatory changes identified through the regional hearings, through solicitations of written comments from the public, or through consultation with HHS staff and (b) advise whether, if effected, these candidate changes would have beneficial results associated with the purpose described above.

As appropriate, the Committee shall consider the potentially most beneficial regulatory reforms and advise regarding their priority for implementation.

STRUCTURE

The Committee shall consist of not more than 30 members including the Chairperson or Co-Chairperson. Appointments shall be made by the Secretary from authorities knowledgeable in the fields of health care delivery, health system operations, advocacy for patients' interest, health insurance, development of pharmaceuticals and other medical products, and biomedical and health services research. Attention shall be given to equitable geographic distribution and to ethnic and gender representation.

Members, including the Chairperson or Co-Chairperson, shall serve from the date of their individual appointments until the termination of the Committee – approximately one year. Should any member be unable to complete his or her term, the Secretary, at his discretion, may appoint a replacement to fill the remainder of the unexpired term.

As necessary, standing and ad hoc sub-committees composed of members of the parent Committee may be established to perform specific functions within the Committee's jurisdiction. The Department Committee Management Officer shall be notified upon establishment of each sub-committee and shall be provided information on its name, membership, function and estimated frequency of meetings.

Management and support services shall be provided by the Office of the Assistant Secretary for Planning and Evaluation.

MEETINGS

The Committee shall meet three times unless, after consultation with the Chairperson or Co-Chairpersons, the Secretary determines that additional meetings are necessary to fulfill the purpose of the Committee. All meetings shall be at the call of Chairperson or Co-Chairpersons. An official of the Federal government shall be present at all meetings.

Meetings shall be open to the public. Advance notice of all meetings shall be given to the public.

Meetings shall be conducted and records of proceedings shall be kept in accordance with applicable laws and Departmental regulations.

COMPENSATION

Members who are not full-time Federal employees shall be paid per diem payments and travel expenses in accordance with Standard Government Travel Regulations.

COST ESTIMATE

The estimated cost for operating the Committee, including travel expenses for members but excluding staff support, is $365,000. The estimated person years of Federal staff support is 1.5 at an estimated cost of $135,000.

REPORTS

The Committee shall present its findings and recommendations regarding reform of HHS regulations to the Secretary in written reports approximately 30 days following each Committee meeting and in a final report upon completion of its tenure. A copy of each report shall be provided to the Department Committee Management Officer.

TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Secretary's Advisory Committee on Regulatory Reform shall terminate by no later than November 30, 2002.

APPROVED:

August 28, 2001 (original);
October 29, 2001 (as amended)
August 6, 2002 (as amended)
Date

Tommy G. Thompson
Secretary

APPENDIX E

LIST OF ACRONYMS USED IN THIS REPORT

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ABN	Advance Beneficiary Notice
ACR	Adjusted Community Rate
ACRP	Adjusted Community Rate Proposal
AIDS	Acquired Immune Deficiency Syndrome
ALJ	Administrative Law Judge
ANSI	American National Standards Institute
AQAS	Alternate Quality Assessment Survey
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CAH	Critical Access Hospital
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CERT	Center for Education and Research on Therapeutics
CFR	Code of Federal Regulations
CHI	Consolidated Health Information
CLIA	Clinical Laboratory Improvement Act
CLIAC	Clinical Laboratory Improvement Advisory Committee
CMS	Centers for Medicare & Medicaid Services
COP	Condition of Participation
COLA	Commission on Office and Laboratory Accreditation
CPT	Current Procedural Terminology
CRNA	Certified Registered Nurse Anesthetist
CSR	Customer Service Representative
DDE	Direct Data Entry
DMERC	Durable Medical Equipment Regional Carrier
DNR	Do Not Resuscitate
DOL	U.S. Department of Labor
E & M	Evaluation and Management (Documentation Guidelines)
EDGAR	Electronic Data Gathering, Analysis, and Retrieval System
EMS	Emergency Medical Service
EMTALA	Emergency Medical Treatment and Active Labor Act
EOB	Explanation of Benefits
ERISA	Employee Retirement Income Security Act
ESRD	End-Stage Renal Disease
FAQ	Frequently Asked Question
FDA	Food and Drug Administration
FDAMA	Food and Drug Administration and Modernization Act of 1997
FFS	Fee-for-Service
FI	Fiscal Intermediary
GAAP	Generally Accepted Accounting Principles
GAO	U.S. General Accounting Office
HAVEN	Home Assessment Validation Entry Software system
HCFA	Health Care Financing Administration (former name for CMS)

HCPCS	Health Common Procedure Coding System
HIPAA	Health Insurance Portability and Accountability Act
HHA	Home Health Agency
HHS	U.S. Department of Health and Human Services
ICD-9	International Classification of Diseases, 9th Revision
IDE	Investigational Device Exemption
IDR	Informal Dispute Resolution
IP	Internet Protocol
IRB	Institutional Review Board
IRS	Internal Revenue Service
IT	Information Technology
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LEP	Limited English Proficiency
LMRP	Local Medical Review Policy
M+C	Medicare+Choice
M+CO	Medicare+Choice Organization
MCAC	Medicare Coverage Advisory Committee
MCR	Medicare Cost Report
MDS	Minimum Data Set
MedPAC	Medicare Payment Advisory Commission
MOU	Memorandum of Understanding
MSN	Medicare Summary Notice
NAIC	National Association of Insurance Commissioners
NBAC	National Bioethics Advisory Commission
NCQA	National Committee on Quality Assurance
NDC	National Drug Code
NF	Nursing Facility
NIH	National Institutes of Health
NPRM	Notice of Proposed Rulemaking
OASIS	Outcome and Assessment Information Set
OBRA 87	Omnibus Budget Reconciliation Act of 1987
OIG	Office of the Inspector General
OMB	Office of Management and Budget
PACE	Program for All-Inclusive Care for the Elderly
PDUFA	Prescription Drug User Fee Act
PET	Provider Education and Training
PHI	Protected Health Information
POL	Physician Office Laboratory
PR	Privacy Rule
QI-1	Medicaid Qualifying Individual (1)
QI-2	Medicaid Qualifying Individual (2)
QIO	Quality Improvement Organization
QMB	Qualified Medicare Beneficiary
RAI	Resident Assessment Instrument
RAP	Resident Assessment Protocol
RAVEN	Resident Assessment Validation Entry Software system
REACH	Regional Education About Choices in Health
RFP	Request for Proposal

RO	Regional Office
RUG	Resource Utilization Group
SA	State Survey Agency
SB	Summary of Benefits
SCHIP	State Children's Health Insurance Program
SEP	Special Election Period
SHIP	State Health Insurance Assistance Program
SLMB	Specified Low-Income Medicare Beneficiary
SNF	Skilled Nursing Facility
SOM	State Operations Manual
SSA	Social Security Administration
SSDI	Social Security Disability Income
SSI	Supplemental Security Income
TMA	Transitional Medical Assistance
URL	Universal Resource Locator
WIC	Women, Infants and Children
Y2K	Year 2000